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QUALITY ASSURANCE GUIDELINES for STD Clinics ~ 1986

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Quality Assurance Guidelines for STD CLINICS - 1986

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U.S. Department of Health and Human Services
Public Health Service
Centers for Disease Control
Center for Prevention Services
Division of Sexually Transmitted Diseases
Training, Education, and Consultation Section
Atlanta, Georgia 30333

Foreword

The first edition of the "Quality Assurance Guidelines for STD Clinics" (QAG) was published in October 1982. This landmark document contained guidelines on STD clinical services derived from over a decade of on-site evaluations of clinics throughout the country and the recommedations of national experts who reviewed drafts prepared by CDC.

The 1985 edition of the QAG has been similarly prepared. It is the product of many clinic reviews using the QAG as a base for comparison of findings and the comments of national experts who kindly reviewed earlier versions. Where the contents of this edition differ from the earlier one, the changes or additions were the result of identifying issues that had not been addressed in the original QAG or the discovery of nuances that needed amplification or clarification. The format of this edition is also different than the earlier one. For consistency, we have made it conform to the structure used with recently published guidelines on other STD program issues.

As with the 1982 edition, the 1985 QAG has several parts. The first provides an outline for clinic structure, management, and medical care. The second serves to guide each clinic in developing its own treatment policies and protocols. The medical protocols include the revised 1985 treatment guidelines for each of the STD discussed. The third contains examples of handouts for patient education, medical records, and protocols currently used by some clinics. These can be adapted to fit each clinic's local environment.

The QAG includes standards that apply to STD clinic structure, management, and medical care. These standards represent the carefully considered judgement of CDC based on nearly two decades of detailed on-site observations made at hundreds of STD clinics around the country. We believe that, in general, these standards are relevant for all STD clinics. Certainly, however, some specific standards may not be deemed appropriate or entirely applicable by an individual STD clinic. We believe that adopting an alternative to a particular standard should be based on a thorough assessment of pertinent data relating to the quality of patient care, disease intervention objectives, and cost- effectiveness considerations in the local setting.

We hope that you will use the 1985 edition of the QAG to continue promoting and maintaining quality clinical services.

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PART I

CLINIC STRUCTURE AND MANAGEMENT

CLINIC STRUCTURE AND MANAGEMENT

A. ACCESSIBILITY

The STD clinic is a key element for the control of sexually transmitted diseases within the community. Ideally, the clinic should provide convenient, confidential, and cost effective clinical services. These services should be organized to minimize any physical, social, or economic barriers encountered by patients seeking care in these clinics. The types of clinical services offered, hours of operation, and location should reflect the needs of the population served by the clinic. Analysis of the demographic characteristics of the population, the proportion of potential patients in school or employed, as well as the geographic locations of the subpopulation with the highest estimated prevalence of sexually transmitted infections within the community may provide useful information for determining the optimal hours of operation. An accurate log of patients seeking care at times other than regular clinic hours may help adjust the hours of service to match the patient demand for services. Since patients attending the clinic are likely to find the hours of operation more acceptable than those not attending the clinic, in-clinic surveys may not reliably assess the appropriateness of the hours of operation. **Each clinic should examine alternative hours of operation and determine those hours which are most convenient for the greatest number of patients.**

Standards

- Clinic hours should meet the needs of the community.
- Clinic hours should be long enough to reasonably accommodate the average daily patient load.
- The clinic should remain open during lunchtime.
- Evening services should be available at least once a week.
- Clinics should be open at least three times a week to allow flexibility in scheduling return visits and sufficient opportunity for symptomatic patients to attend.
- If the population of STD patients is too small to justify this number of hours, then clinics should incorporate STD services into other clinics (e.g., family planning, adolescent health) that are located in the same building.
- Clinics, particularly new ones, should be located near residential areas of high STD prevalence and be readily accessible to public and private transportation.
- Ideally, clinic services should be free. If necessary, fees should be minimal or on a sliding scale. Services and/or medications should never be withheld because patients cannot pay a fee.

B. CLINIC ENVIRONMENT

The quality of the physical facility as well as the attitudes of staff will influence a patient's impression of clinic services.

1. Clinic Directions:

Standards

- The building that houses an STD clinic should have easily readable signs at street level, in the registration area, and at points in between that clearly direct patients to clinic.

2. Waiting Areas:

Standards

- Waiting areas should be clean, maintained at a comfortable temperature, and large enough to accommodate all patients.
- Waiting areas should be constructed such that registration information can be obtained in a confidential manner.
- Waiting areas should have posters, pamphlets, and/or audiovisuals that list clinic hours, summarize what patients should expect in the clinic, and provide patient education.
- Waiting areas should contain easily accessible patient educational handouts stressing disease intervention behaviors: (e.g., take medications properly, return for test-of-cure (TOC), avoid sex until after TOC, bring sex partners for treatment, seek treatment early if symptoms occur in the future, use STD-preventive measures, especially condoms, when having sex).
- Except in facilities where the STD patients wait in a common area with patients attending clinics other than the STD clinic, the concept of confidentiality should be promoted by using numbers rather than names when patients are called from the waiting areas for services.

3. Examination Rooms:

Standards

- Exam rooms should be clean, private, and sufficiently separated from the waiting area so it is not possible to overhear or to see patients who are being examined.
- The number of exam rooms should be adequate to accommodate the maximum number of patients and clinicians (at least one room per clinician).
- Exam rooms should have adequate equipment and supplies for physical exams and specimen collection for both male and female patients. The clinic should have an effective system for monitoring and replenishing supplies. (See checklist of items in Appendix I.)

4. Patient Consideration:

Standards

- In all interactions with patients and with other staff, clinic personnel should be courteous and respectful of individual dignity.
- Cross-cultural awareness and bilingual fluency (where appropriate) should be promoted as crucial elements in establishing a positive clinic-patient relationship.

C. REGISTRATION PROCESS

Registration should not be the "bottleneck" of STD clinics. A well-trained clerical staff and a well-organized clerical system will expedite patient flow at this critical station. Since registration personnel see patients first, they will set the tone for the visit. They must be sensitive to their role in influencing patient attitudes.

Standards

- Patients need to provide accurate personal identification and locating information. In clinics where patients frequently give false personal identifying and/or locating information, positive identification should be required at registration. (Patients unable or unwilling to provide such positive identification should be referred for counseling about the need to provide accurate information to the Clinic Manager before being registered).
- To prevent waiting patients from overhearing registration interviewing, registration desks should have acoustical barriers separating them from waiting areas. If physical barriers are not possible, registration clerks should reduce sound transmission by lowering their voices, keeping waiting room chairs as far away as possible, not letting patients crowd behind one another in line, etc.
- Clinics should have sufficient clerical staff to register patients expeditiously and to keep registration open continuously by staggering lunch hours and breaks.
- Where privacy is a problem, as an alternative the clinic should consider a self-registration process where no personal information is exchanged verbally.
  - — While preparing the medical records, registration clerks should collect only relevant identification and demographic data and enter it on the records and routine laboratory request forms. Clerks should determine whether the patients are in the right clinic and record whether they are attending because of referral or appointment, or their names appear in the disease intervention ("expected-in") file. Clerks should avoid asking the medical reason for the visit and any discussion of symptoms or medical history. They should assign patients clinic numbers by order of arrival and should assure that each patient and medical record arrive together at the next clinic stop. Clinics should establish ways (e.g., issuing a letter instead of the next number in sequence) to signify those patients who are to receive expedited care.
  - — Registration clerks should give patients oral information and "welcome-to-clinic" handouts about what to expect in clinic, e.g., clinic hours, fees, confidentiality, brief description of physical exam, lab tests and turnaround times, time and phone number to call for lab results, and the fact that patients may sometimes be called out of turn if their evaluation is expected to be of very short duration.
  - — Reporting test results to patients: Clerks are often designated to report results of lab tests to patients who telephone the clinic. To protect confidentiality and avoid revealing test results to unauthorized persons, staff should require callers to identify themselves by name, clinic number, date of visit, and other identifiers not likely to be known by an acquaintance.
- Clinics should have special, rapid registration procedures for patients attending for followup examination, TOC, repeat STS, or "disease intervention emergencies" e.g., sex partners or other high priority referrals from Disease Intervention Specialist (D.I.S.).

D. MEDICAL RECORDS

The format, composition, and maintenance of medical records are crucial to the ability of an STD clinic to provide and assure quality care for patients.

1. Design/Contents:

Standards

- Records should have a "check-off" design with a sufficiently complete set of symptoms, history, physical examination findings, diagnoses, treatment, and appropriate lab tests to cover all common STD. "Other" or "specify" categories should be provided for less common STD and lab tests or medical problems other than STD.
- Medical records should contain sufficient demographic information to identify the patient and rapidly locate the individual.
- Medical records should contain sufficient information in all clinical evaluation categories so that any clinician who looks at a record will understand the examining clinician's assessment. These categories include reason for visit, medical/sexual history,* physical findings, laboratory tests ordered and performed, diagnosis, treatment, counseling, and plans for followup or referral.

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* Caution should be observed on including certain aspects of medical/sexual history (i.e., number of sexual partners in the past month, specific exposure sites, sexual preference, and sexual practices) that the confidentiality statute of the jurisdiction is sufficiently strong to avert the reasonable possibility that the record could be obtained through a subpoena. If the records are not so protected, this information could leave patients vulnerable in civil or criminal court proceedings.

- The list of items in each of the above clinical evaluation categories of the record also should be complete enough to guide any examining clinician through a thorough subjective and objective evaluation of the patient.
- Additional space should be allotted for a brief narrative description of items not covered in the evaluation categories.

2. Capacity for Quality Assurance Audit:

Standards

- The clinical evaluation and laboratory items on the record should be designed so that clinicians are required to mark each as to whether it is positive or negative, done or not done, normal or abnormal, etc., so that a quality assurance audit of records can determine whether or not clinician performance is consistent with established guidelines and clinic protocols.

3. Filing System:

Standards

- Medical records should be kept in coded filing folders along with lab reports, referral forms, and other pertinent information.
- Medical records should be stored in locked files where they can be easily located by clinic personnel but are inaccessible to unauthorized persons.
- Medical records stored on computer need to have rigorous access protection procedures to prevent unauthorized entry into the file, as well as a back-up filing process to prevent any loss of information.

4. Purging:

Standards

- Clinics should follow a formal procedure for purging medical records (see Appendix H).

E. CLINIC FLOW

Clinic flow should be organized for effective use of personnel and physical facilities. The sequence should be logical and avoid any patient confusion or unnecessary delays.

1. Required Patient Stops:

In general, flow is most efficient when patients make a minimum of stops. Except for those who are to receive expedited care, patients should be seen in the order that they present for care, regardless of sex. Registration, clinical care, and an interviewing/counseling session are the three basic stops. Additionally, secondary waiting room stops may be required if there is a shortage of examination rooms or while patients are awaiting stat lab results. These stops should be kept to a minimum.

A patient should not have to repeat his/her medical history to other staff members before seeing the clinician. Ideally, the clinical care stop (with a single nurse, physicians assistant, or physician) should include history-taking, blood and other laboratory specimen collection, exam, diagnosis, treatment, and counseling regarding therapy, followup, and preventive measures to avert future infection. Clinicians can draw a blood specimen after taking the history or during the physical exam.

Standards

- Clinic flow should be organized such that the next available clinician sees the next patient in order, regardless of sex or complaint.
- Clinic flow should be organized so that patients make a maximum of three stops (registration, clinical care, and an interviewing/counseling session.)

2. Patient Waiting Time:

Ideally, waiting time from registration to treatment for initial visit patients ("volunteers") should be 1 hour or less. Shorter waiting time should be offered to followup and test-of-cure (TOC) patients for two reasons: (1) The time required to examine them usually is shorter, thus making it efficient to get them processed quickly; and, (2) shortened waiting encourages compliance with followup and therefore leads to better disease control through earlier discovery of treatment failures, non compliance, or reinfection. This service may be compared to the express line which many commercial establishments have provided for the convenience of customers doing limited business.

Standards

- Initial patient visits should take 1 hour or less from registration to treatment.
- Procedures should be established to accord expedited care to followup and test-of-cure patients.

3. Appointment vs. Walk-In Systems:

A combined appointment and walk-in system is a proven method to help smooth out patient flow. Clinicians may be assigned on a rotating basis to see walk-ins or appointments. Volunteer patients phone for appointments either a few days before the visit or on the morning of the visit. Usually, registration clerks keep the appointment books and schedule appointments both for patients who phone in and for patients instructed by the clinicians to return for followup or TOC. For the latter patients, clinicians may also write the appointment slip themselves and send a copy to the registration clerk, who records the appointment in the book. Patients referred in by the D.I.S. can often be scheduled ahead of time by one of the above mechanisms. Some clinics may choose to schedule TOC patients to be seen at times when no physician is present, since most of these patients may not need repeat diagnostic evaluation or treatment. When patients with complicated problems (that will require a large block of clinician time) are referred by D.I.S. or other staff, the referring staff should discuss the case ahead of time with the clinician and schedule the appointment at a convenient time.

The major factor that makes an appointment system work is an assurance that patients will experience a shortened waiting time when they keep their appointments. Often, minor changes in patient stops and floor space utilization will allow appointment patients to be seen promptly without upsetting walk-in patients who arrived before them. However, walk-ins should be made aware that they will be seen more quickly if they make appointments.

Standards

- Any clinic with an average patient volume exceeding 3 patients per clinician per operating hour should adopt a combined appointment and walk-in system to smooth out patient flow.
- A procedure should be established to accord expedited care to any patients referred by a D.I.S.

F. CLINIC MANAGEMENT STRUCTURE

Clinics should have one person, the clinic manager, with authority to develop and implement clinic goals, policies, and procedures, as well as manage personnel, orchestrate all clinic functions, and assure quality of care.

Standards

- Job qualifications for clinic managers should include:
  - — Adequate medical training to make valid comparisons between the clinic protocols and the directly observed quality of care provided by clinicians (e.g., nurses, physicians, physicians assistants) or, in the case of a nonmedical clinic manager, adequate medical knowledge to make valid comparisons between the clinic protocols and the findings of a medical professional (e.g., clinician-in-charge) delegated to directly observe and evaluate the quality of clinician care. Completion of at least the STD clinician training course - Comprehensive, a 2 week course offered at STD Prevention/Training centers around the country, should be required for any clinic manager, and for a medically trained clinic manager, clinical experience in treating STD should be required.
  - — Adequate management training to effectively orchestrate clinic management. This should include completion of at least the CDC course, STD Clinic Administrator/Manager Seminar.
  - — Adequate orientation to STD disease intervention outreach concepts and activities to validly judge the needs and performance of D.I.S. staff.
- Responsibilities of Clinic Managers should include development, implementation and continual updating of clinic goals, policies, procedures, and performance standards. This includes developing and continually updating a clinic manual and assuring that all staff know and use it. (Essential elements of clinic manuals are outlined under G. below).
- Manage personnel responsibilities which should ensure that:
  - — The clinic has adequate staff to care for the patient population (a method for calculating the number of clinicians needed for clinic can be found in Appendix M). Work and vacation scheduling is coordinated to avoid gaps in clinic staffing.
  - — All staff have appropriate job descriptions and know what is expected.
  - — All staff are adequately trained and regularly updated in STD management. (Optimally, all clinicians should complete the STD Clinician Training Course - Comprehensive).
  - — All staff follow clinic protocols and standing orders correctly.
  - — All staff meet performance standards.
  - — All staff work together cooperatively to provide the best possible patient care (this may involve identifying and settling personnel disputes before they are magnified, redefining staff roles to meet changing clinic needs, etc).
  - — Input from staff is encouraged and, when appropriate, their suggestions for adding new policies or changing old ones are adopted.
  - — Important information is communicated to all staff through regular (e.g., at least twice monthly) staff meetings.
- Oversee quality assurance procedures (see "Formal Quality Assurance Procedures" on Page 18).
- Ensure that the clinic facility, including equipment and supplies, is adequate to meet the needs of the patient population.

G. CLINIC MANUAL

Clinic manuals may initially be developed based on this document. Federal government publications do not have a copyright; therefore, any area may reproduce or reprint these QAG under its own name, and expand them with administrative memoranda and other local policies and procedures issued by the clinic manager, the local health department, or other appropriate administrators. Thereafter, the manual may be further revised to meet local needs.

Standards

- An STD clinic manual should include the following elements:
  - — Goals and objectives of the clinic.
  - — Job descriptions and performance standards for all staff. These should include:
    1. Qualifications and training requirements for each job.
    2. The role each job plays in the operation of the clinic.
    3. A description of the tasks required for each job.
    4. The mechanism for evaluation of the performance of these tasks. (See Appendix C for an example of a standardized form for evaluating clinicians and Appendix D for a sample form for evaluating registration clerks during their interactions with patients.)

5. Attitudes expected to be conveyed toward clinic patients.

— Protocols for:

1. Patient evaluation, diagnosis, and management of all STD.
2. Followup to therapy.
3. Emergency procedures.
4. Counseling/education.
5. Medical consultation for nonphysician clinicians.
6. Referral to outside agencies.
7. Referral of women for PAP smears, if not done routinely by the clinic.

NOTE: These protocols are outlined in detail on pages 7-10.

— Standing orders for non-physician clinicians.
— STD Treatment Guidelines. (These should comply with CDC's STD Treatment Guidelines.)
— Locally determined policies and procedures, such as frequency of staff meetings, fire drill instructions and frequency, etc.
— Procedures for formal Quality Assurance.

H.CLINICIAN ROLES AND PERFORMANCE STANDARDS

1. Clinician Roles

Since properly trained and adequately supervised nonphysician clinicians can manage most uncomplicated STD, the use of nonphysician clinicians is a more cost-effective staffing pattern. Having a single clinician manage each patient minimizes fragmentation and impersonal interaction, and improves patient flow and satisfaction. For these reasons, nursing roles should be expanded and not be limited to history-taking, assisting physicians, and dispensing medications. With adequate physician back-up, trained and experienced nurses may manage the whole clinical care process.

Standards

- Nurses should function as clinicians responsible for the entire clinical care stop (history taking, physical exam, laboratory specimen collection, diagnosis, treatment, and plan for followup) according to clinic protocols.

2. Performance Standards

In addition to completing the CDC STD Clinician Training Course - Comprehensive, new clinicians (both physician and nonphysician) should be evaluated by the clinic manager and the physician(s) primarily responsible for patient care. This should assure that they are capable of adequately evaluating, diagnosing, and treating STD patients according to clinic protocols. In many cases, it may be necessary for physicians and/or experienced nonphysician clinicians to precept these new clinicians until both are satisfied that their skills and judgment meet quality assurance standards. A preceptorship for clinicians other than physicians may be needed for skills acquired only by evaluating large numbers of patients (e.g. bimanual pelvic exams). Decisions that require a high level of judgment should be made in consultation with a physician. Clinicians not yet skilled in performing bimanual examinations may be used initially to see test-of-cure patients. Such patients often require only a culture and not a repeat examination (if their initial examinations were normal and they have no new symptoms), and this approach to serving them also may expedite patient flow. It may be expedient for clinics to require nonphysician clinicians to satisfactorily complete this preceptorship before qualifying them to care for patients under protocols and standing orders in the absence of a physician. In such cases, the clinic may elect to include a statement of "clinical privileges" signed by preceptee, physician-in-charge, and clinic manager in the preceptee's personnel folder. (See Appendix C for an example of a standardized form for evaluating clinicians and Appendix D for a sample form for evaluating registration clerks by direct observation during their interactions with patients.)

Standards

- Nonphysician clinicians should receive training at an STD Prevention/Training center and should be subject to a period of preceptorship under an experienced clinician.

I. CLINIC PROTOCOLS FOR PATIENT MANAGEMENT

1. Patient Evaluation

Information should be collected in a manner that establishes rapport between the patient and clinician, assures accurate definition of the problem(s), and leads to successful patient management.

Standards

- The basic medical history should include:
  - — Reason(s) for the visit.
  - — A description of symptoms:
    1. Onset, duration, character, and frequency.
    2. Relationship to sexual intercourse and urination.
    3. Prior history of similar problems.
    4. History of similar or other problems in a sex partner.
  - — History of prior sexually transmitted infections and treatment with dates.
  - — Medication history:
    1. Recent antibiotic use: type, purpose, duration.
    2. Known drug allergy: drug, type of reaction, and date.
    3. Other current medications: type, purpose, date, and duration.

— Review of recent sexual activity:
1. Time since last sexual exposure.
2. Number of partners in past month*.
3. Sexual preference(s)*.
4. Sites of sexual exposure (oral, genital, anal)*.
5. Sexual practices (specific practices which may predispose to disease)*.

— 6. Use of condoms (counseling about condom use could occur at this point).

— In women - reproductive history:
1. Last menses.
2. Unusual aspects of last menses (change in the amount of flow or duration, pain, etc.).
3. Contraception (the need for contraception counseling should be assessed at this point and the appropriate referrals made).

- The basic physical examination should include:

— For women:
1. General inspection of skin with attention to the face, trunk, forearms, palms, and soles.
2. Inspection of oral cavity and mucosal surfaces.
3. Complete pelvic examination, including:
   a. Inspection of the external genitalia and perineum for lice, nits, discharge, masses, lesions, tenderness, etc.
   b. Inspection of the cervix with particular attention to the presence of discharge, as well as to the amount, color, and character of the discharge. The appearance of the cervix should be carefully noted with attention to the presence of ectopy, edema, and friability.
   c. Inspection of the vaginal mucosa with attention to the amount, color, and character of any discharge, as well as to any lesions present.
   d. Bimanual examination—with attention to cervical motion tenderness, uterine enlargement, adnexal tenderness, and pelvic masses.
   e. Inspection of the anus.
   f. Palpation of the uterus, adnexae, and rectum during the rectovaginal exam.
4. Palpation of the Bartholin's glands, and when a Bartholin's absess is noted, palpation of the Skene's glands.
5. Palpation of the inguinal and femoral areas for lymphadenopathy. If nodes are found, the cervical, supraclavicular, epitrochlear, and axillary areas should also be palpated for lymphadenopathy.

— **For men:**
1. Inspection of skin with attention to the face, trunk, forearms, palms, and soles.
2. Inspection of the oral cavity and mucosal surfaces.
3. Inspection of pubic hair for lice and nits.
4. Inspection of penis with attention to the meatus, retraction of foreskin, and expression of any discharge from urethra—the color, amount, and character should be noted. Penile lesions should be well described.
5. Inspection of the scrotum and palpation of the contents with attention to testicular tenderness and masses.
6. Palpation for inguinal and femoral areas for lymphadenopathy; if nodes are found, the cervical, supraclavicular, epitrochlear, and axillary areas should be palpated for lymphadenopathy.
7. Inspection of the perianal area

— For men with sex partners of the same sex, the following additional items should be included:
1. Inspection of the oral cavity and mucosal surfaces, with particular attention to oral lesions.
2. Palpation of the cervical, supraclavicular, epitrochlear, and axillary areas for lymphadenopathy.
3. Inspection of the anus and perianal area.

- Routine laboratory specimens include:

— **For women:**
1. Cultures for gonorrhea from the endocervix regardless of time in the menstrual cycle (also from the urethra if the cervix is absent or if a urethral discharge is present). Anal cultures, in addition, may increase the yield of positives, whether the anus has been exposed or not.
2. Oropharyngeal culture for gonorrhea in patients with a history of oral exposure.
3. Endocervical Gram stained smears for intracellular diplococci are highly specific and therefore, if positive, provide immediate evidence of infection, thus justifying immediate treatment. (However, because of low sensitivity, negative endocervical Gram stains do not exclude the possibility of gonorrhea. Therefore, such smears should be used as an adjunct to, but not as a substitute for endocervical cultures and is not advised as a routine screening tool.
   Table 1 summarizes the sensitivity and specificity of Gram stained smears from anogenital sites).
4. Endocervical Gram stained smears may also be useful for evaluating women with suspected *Chlamydia trachomatis* infections. The presence of 10 or more white blood cells (PMN) per oil immersion field on Gram stained smears correlates with the presence of mucopurulent cervicitis which may be due to infection with *C. trachomatis*.
5. Cultures for chlamydia (if available, or antigen detection test if culture is not available) from the endocervix regardless of time in the menstrual cycle (also from

* See the footnote on page 4. While this information should be routinely pursued as part of the history taking process for each patient, recording it on a medical record should occur only in jurisdictions where the confidentiality statute either explicitly or implicitly, but clearly, exempts the record from subpoena.

the urethra if the cervix is absent or if a urethral discharge is present) in women who would not otherwise be treated for *C. trachomatis* infection.

6. Serologic test for syphilis (STS) at every visit unless there is documentation of a negative test within the previous 30 days.
7. Pap smear or referral for Pap smear if not done within past year, or if most recent Pap smear was abnormal.

— For men:

1. A urethral Gram stain when a utrethral gonococcal infection is suspected. A culture should be obtained if Gram-negative intracellular diplocci cannot be identified on direct smear or when urethral exudate is absent. If antibiotic resistance is suspected, a culture is necessary regardless of the Gram stain results. If exudate can be expressed through the urethral meatus, the exudate can be transferred on a cotton-tipped or calcium alginate swab to a slide for Gram stain and then to selective culture medium with the same swab. If no exudate can be expressed, a specimen should be obtained for smear and culture by inserting a calcium alginate swab 2-3 cm into the anterior urethra.
2. Urethral Gram stained smears also are useful for evaluating men with suspected *Chlamydia trachomatis* infections. The presence of 4 or more white blood cells (PMN) per oil immersion field on Gram stained smears correlates with the presence of urethritis which may be due to infection with *C. trachomatis*.
3. Gonorrhea cultures should be obtained from all exposure sites if intracellular diplococci are not seen on a smear or if one is not performed, if history or referral suggests possible exposure to gonorrhea, in medico-legal situations, if penicillin-resistant gonococci are endemic in the clinic population, or if treatment failures occur in areas not considered endemic for penicillin-resistant gonorrhea.
4. Oropharyngeal and/or rectal cultures for gonorrhea should be obtained if the history indicates exposure or symptoms. Comment: Gram-stained smears of the oropharynx for gonorrhea may be misleading due to the presence of commensal Neisseria and therefore are not recommended. Gram stain smears of the rectum taken using blind swabs are not very sensitive for gonococcal infections and are not recommended. However, Gram stains of selective smears taken from the rectum at the time of anoscopic examination may be more sensitive and may be useful.
5. Cultures for chlamydia (if available, or antigen detection test if culture is not available) from the urethra in men who would not otherwise be offered chlamydial treatment.
6. STS at every visit unless there is documentation of a negative test within the previous 30 days.

TABLE 1 - Sensitivity and Specificity of Gram-stained Smears for Detection of Genital or Anorectal Gonorrhea

Site and Clinical Setting	Sensitivity*	Specificity*
Urethra:		
Men with symptomatic urethritis	90-95	95-100
Men with asymptomatic urethral infection	50-70	95-100
Endocervix:		
Uncomplicated gonorrhea	50-70	95-100
Pelvic inflammatory disease	60-70	95-100
Anorectum:		
Blind swabs	40-60	95-100**
Anoscopically obtained specimens	70-80	95-100**

*Sensitivity = percent of patients with positive cultures who have positive Gram-stained smears. Specificity = percent of patients with negative cultures whose Gram-stained smears also are negative.

**The studies showing 95-100 percent specificity for anorectal smears did not report whether meningococcal infection was distinguished from gonorrhea. Until further data are available, a positive anorectal smear should be considered highly specific for either gonococcal or meningococcal infection.

Source: Hansfield, HH, Chapter 19, Gonorrhea and uncomplicated gonococcal infections. in *Sexually Transmitted Diseases.* Holmes K, Mardh P, Sparling F, and Wiesner, P (eds), New York, McGraw Hill, pp. 213

- Additional evaluation is indicated when routine history and/or physical findings suggest:
  - — Pelvic inflammatory disease, mucopurulent cervicitis, or high risk groups (e.g., urban, sexually-active adolescent women): endocervical Gram stain, culture for gonococci, and (if available) cultures for *Chlamydia trachomatis.*
  - — Vaginal discharge: pH, "sniff test" for amine odor, saline mount for trichomonas and clue cells; KOH mount for yeast (and/or Gram stain for yeast and clue cells); and endocervical Gram stain and culture for gonococci.
  - — Suspected pregnancy: pregnancy test, if available.
  - — Chlamydia associated syndromes, i.e., nongonococcal urethritis (NGU), mucopurulent cervicitis (MPC), epididymitis, PID, and sex partners of patients with chlamydia associated syndromes: chlamydia testing (if available).
  - — Sex partners of patients with *Chlamydia trachomatis*: Chlamydia testing (if available).
  - — Unexplained cervical or vaginal lesion: darkfield and Pap smear.
  - — Any sex partner of a confirmed or suspected syphilis patient: immediate RPR card test.
  - — Any lesion thought to be a chancre: serous fluid from lesion for darkfield examination; immediate RPR card test.
  - — Any rash thought to be secondary syphilis: serous fluid from lesions (if possible) for darkfield examination; immediate RPR card test.

— Other STD: see specific diagnostic tests in the "STD Medical Protocols" section that follows.
— Increased risk for hepatitis B: If available, Hepatitis B serologic test and/or vaccination or referral (e.g., gay or bisexual men, health care workers).
— Increased risk for HTLV-III infection: If requested, HTLV-III antibody serologic test, if available.

2. Patient Management

Standards

- After appropriate history, physical exam, and lab testing, clinicians should plan treatment and followup using the "STD Medical Protocols" section that follows as a reference.

3. Indications for Medical Consultation for Nonphysician Clinicians and Referral for Other Health Services

Occasions will arise when STD clinicians, especially nonphysician clinicians, will need medical consultation. These should be anticipated in clinic protocols with explicit instructions related to each. Additionally, the history and examination of a patient often will indicate the need for health services beyond the scope of the STD clinic. For such instances, the clinic should maintain a current list of community referral resources. This will assist the staff in counseling patients on how to obtain the needed evaluation. In urgent situations, telephone consultation with providers can facilitate patient management. In less urgent situations, written consultation requests are likely to assure that patients obtain the necessary appointments. These also serve to promote communication among community medical care providers. Providers for which the clinic should have current addresses and telephone numbers include medical specialists (family practitioners, obstetricians-gynecologists, urologists, pediatricians, internists, dermatologists, surgeons, proctologists, etc.), family planning clinics, free clinics, hospitals, mental health centers, and local emergency medical services.

Standards

- Physician consultation is indicated when:
  — Pelvic inflammatory disease (PID) is clinically suspected.
  — Other pelvic examination abnormalities (uterine enlargement, adnexal masses, etc.) are found.
  — Because of severity of disease or uncertainty of diagnosis, in-hospital rather than outpatient evaluation and treatment may be necessary.
  — Pelvic examination could not be conducted satisfactorily (regardless of reason).
  — Tender or enlarged Bartholin's glands are present in females.
  — Tender or enlarged epididymides or testicles are present in males.
  — The patient is under age 14.
  — The patient requests a physician consultation.
  — Any sign of an adverse reaction to treatment occurs, such as:
    1. Anaphylaxis (angioedema, urticaria, bronchospasm, hypotension, and/or pruritus).
    2. Procaine reaction (seizures, psychosis, mania).
    3. Skin rash.
    4. Anxiety (hyperventilation, fainting, distal paresthesias).
- Patient referral to a specialist may be indicated when:
  — The specialist required is not available in the clinic.
  — A patient with acute salpingitis (PID) is believed to need inpatient care. Criteria for making this judgment include:
    1. Severe illness (including nausea and vomiting).
    2. Uncertain diagnosis.
    3. The differential diagnosis includes a surgical emergency.
    4. Laboratory testing which is necessary but unavailable in the clinic.
    5. Significant pelvic mass or abscess.
    6. Pregnancy.
    7. Failure to respond to outpatient therapy.
  — A severe drug reaction occurs requiring further treatment or observation.
  — A pregnant patient is not receiving prenatal care. (Comment: pregnant patients who are infected with STD or are sex partners of patients with STD should be treated *while in STD clinics*, according to CDC Treatment Guidelines for pregnant patients, and then referred for prenatal care.
  — The woman is sexually active and uses no method of contraception, requests contraception services, or inquires specifically about a vasectomy or tubal ligation.
  — IUD removal is medically necessary.
  — A patient has unacceptable side effects with her current contraceptive.
  — Nongonococcal urethritis does not respond to medical therapy.
  — Symptoms suggesting a urinary tract infections appear to recur.
  — Prostatic disease other than acute prostatitis is suspected.
  — Other urological disorders are recognized (e.g., varicocele, phimosis, hypospadias).
  — A general surgical evaluation is desired for such findings as an inguinal hernia, hemorrhoids, or extensive warts.
  — The clinic physician determines that specialty consultation is needed.

4. Followup to Therapy

Ensuring that a diagnosed patient is cured of infection is crucial to disease intervention. When a patient defaults on extended therapy or if the therapy fails for some reason, their infection continues, their infectious state can recur, and disease intervention is negated. This can be minimized through assertive treatment compliance counseling, encouraging patients to return for treatment followup, and performing high quality followup examinations.

Standards

- History should include:
  - — Symptom response and current problems.
  - — Reaction(s): allergic, Herxheimer, gastrointestinal, others.
  - — Adverse reactions to drugs—describe symptoms.
  - — Compliance with previous instruction.
  - — Sexual exposure since therapy.
  - — Treatment status of sex partner(s).
- The clinician should assess the positive physical findings of the first evaluation and any new complaints.
- Laboratory followup varies according to the diagnosis. The basic principle is that laboratory data provides a guide for the clinician to monitor the efficacy of the therapy. For each STD suggested, laboratory followup is included in the "STD Medical Protocols" section.
- The TOC return rate for gonorrhea in both males and females should be over 60 percent.
- Over 70% of patients diagnosed in clinic who have PID should return within 2 to 3 days of initial diagnosis for re-evaluation examination.

5. Emergency Procedures

STD clinics must be prepared for medical emergencies, particularly life threatening adverse drug reactions. The best way to be prepared is to have established procedures, adequate and properly maintained equipment, and appropriately trained staff.

Standards

- A suggested protocol for emergency medical care appears in Appendices J and K. A copy of this protocol should be kept in the clinic *with the emergency supplies* as well as in each exam room. All staff should be familiar with it.
- A suggested list of emergency equipment, supplies, and medications appears in Appendix K. Emergency items should be checked and updated frequently according to an established schedule (e.g. once a week). The clinic manager should designate responsibility for this task to a single clinic employee, who should sign his/her name to the supplies list each time he/she checks supplies. This responsibility can be rotated so that all staff remain familiar with the equipment, supplies, and medications. Emergency supplies should be sealed when not in use or being checked, to assure that no one depletes them.
- Ideally, all clinical staff should be trained in cardiopulmonary recuscitation (CPR) and, at a minimum, should know what to do in emergencies. If a physician is not on-site, at least one clinician must be certified in advanced CPR skills within the last 12 months.
- Emergency drills should be held at least every 6 to 12 months to assure that all staff (medical, clerical, laboratory, and D.I.S.) can recognize emergencies, know their roles and the chain of command, know the location and contents of emergency supplies and protocols, and can use all equipment properly.

6. Counseling/Education

Patient counseling and education, designed to influence disease intervention and prevention behaviors, involves the entire clinic staff. Handouts designed for easy comprehension are an efficient way of giving the patient basic information. Reinforcing the main points in the handout is important, but the only way to assure that the patient understands the condition and his/her role in its management is through active patient counseling.

Standards

- The clinic staff should impart sufficient information, in terms understandable and acceptable to patients to assure that patients have accurate perceptions of their diseases and what the treatment regimens are. This information includes:
  - — Results and interpretation of all tests (e.g., a negative test does not necessarily mean the absence of infection).
  - — The name of the patient's disease and its importance.
  - — The names of the medications and why they are used.
  - — How much medicine and when, specifically, to take it. What to do if doses are missed.
  - — The expected outcome of treatment.
  - — Potential side effects and what to do about them.
  - — Description of behaviors and conditions that will assure treatment efficacy and avoid side effects of treatment (e.g., taking tetracycline on an empty stomach, the interaction of metronidazole and alcohol).
  - — Symptoms of and appropriate response to apparent treatment failure.
- The clinic staff should stress the importance of evaluating the patient's sex partners and make sure the patient understands:
  - — How the disease is transmitted and its incubation period;
  - — The time of infectiousness.
  - — The consequences to the health of the patient and partner(s) if not medically evaluated;
  - — That the sex partner(s) needs to obtain medical evaluation and treatment from a provider or facility offering appropriate STD care;
  - — The likelihood of asymptomatic infection; and
  - — The necessity of abstaining from sex until partners obtain medical evaluation.
- At the time of the treatment followup visit, most patients should be counseled concerning:
  - — The necessity for followup tests. Patients are reminded that the clinic expedites registration and examination for followup patients.
  - — When and where they will take the tests.
  - — Potential consequences of not obtaining the tests.
- The disease intervention messages patients receive from clinic staff include how to prevent future infections and how to prevent transmission if they suspect they have STD. Key points the staff should teach and reinforce to patients are:
  - — That reinfection can occur easily, so patients should:
    1. Avoid sex with their sex partners until they and their sex partners are free of disease; and
    2. Stop having sex and seek care promptly for self and any partners if symptoms recur.
  - — That patients should understand the major signs and symptoms of STD infection and that asymptomatic in-

fection can occur. So when STD infection is suspected, individuals should:
1. Stop having sex; and
2. Seek prompt examination for self and any sex partners

— That protection from STD is provided by:
1. Proper and consistent use of condoms.
2. Monogamy*; and
3. Abstinence*;

- Handouts should be of two basic types:
  - — General handouts for patients to read prior to their diagnosis. Several messages should be provided: Take medication(s) as directed; return for followup if directed; respond promptly to symptoms or the suspicion of infection; and practice prevention. These messages reinforce the messages that should be given to the patient by clinic staff (see above).
  - — Disease-specific and treatment-specific handouts that reinforce verbal explanations of diseases, treatments, plans for followup, etc., to be kept in exam rooms and given by clinicians to patients after diagnosis.

J. CLINIC STAT LABORATORY

An on-site laboratory prepared to perform immediate (stat) high quality testing to assist with the diagnosis of various STD is an indispensable component of any contemporary STD clinic. Such testing can be performed by a qualified technician or by clinicians themselves if they have been trained and can legally perform the procedures. Such training is part of various courses taught at STD Prevention/Training centers.

Standards

- Each clinic should have an on-site stat laboratory.
- The stat laboratory, at a minimum, should perform the following tests:
  - — Gram stain—for gonorrhea as well as for white blood cells (PMN) for nongonococcal urethritis and mucopurulent cervicitis.
  - — Rapid plasma reagin (RPR) card test for syphilis.
  - — Darkfield examination for syphilis.
  - — Saline wet mount for trichomoniasis, *Gardnerella vaginalis*, and yeast infections.
  - — KOH prep for yeast infections.
- The stat laboratory should, at minimum, have the following equipment (along with appropriate antigens, supplies, and glassware for testing):
  - — Brightfield microscope.
  - — Darkfield microscope (or darkfield condenser for the brightfield scope).
  - — Adjustable RPR card rotator.
  - — Small centrifuge.
  - — Incubator.
  - — Refrigerator.
  - — Sterilization equipment (Bunsen burner, electric sterilizer, or alcohol lamp).
- The stat laboratory should have the accessible backup of a reference laboratory for the performance of test procedures that further assist in the diagnosis of STD seen among population groups using STD clinic services.
- The stat laboratory should maintain complete and current logs/records of testing activities, results, and results of backup/confirmation testing by the reference laboratory.

* To ensure maximum educational impact and patient acceptance of any preventive measure (i.e., condoms), clinic staff should present these two options with professional objectivity and carefully avoid any suggestion that they should be considered on religious or moral grounds.

K. DISEASE INTERVENTION OUTREACH STAFF

Integral to the success of an STD clinic operation is the interrelated disease intervention outreach work performed by Disease Intervention Specialists. D.I.S. build upon the patient management skills of the STD clinician by reinforcing the patient education counseling provided by the medical staff. Moreover, they are responsible for managing the referral of sex partners and others at risk of infection. Both activities are designed to interrupt disease transmission in the community and to assist individual patients in averting reinfection. Thus, effective communication of disease intervention information between the clinician and D.I.S. is of paramount importance. Likewise, the transition for patients between services which the clinician provides and the interviewing/counseling session with a D.I.S. must be smooth and appear to be natural extensions of each other. D.I.S. are highly skilled professionals who understand the patient's need for confidentiality and the social sensitivities associated with STD. Local health departments should not only maximize their capabilities within the public STD clinic setting, but offer their services as well to private physicians and community health facilities.

Standards

- D.I.S. are available on-site or on-call to provide disease intervention outreach services during the hours of clinic operation.
- Clinic procedures are established such that all relevant disease intervention information is smoothly exchanged between D.I.S. and clinical staff.
- Clinic protocols specify which STD patients are to receive services from D.I.S.
- For patient whom protocols specify are to receive services from a D.I.S., the clinician provides appropriate preparation (the details of which are established by D.I.S. staff through their supervisor) and personally makes introductions so it is reasonable for patients to conclude that D.I.S. services are an integral part of their process of STD care.

L. FORMAL QUALITY ASSURANCE PROCEDURES

Quality Assurance has several very important purposes, including:
1. By consensus, to establish criteria for excellence in patient care that meet accepted national and local standards;
2. Through peer review and other auditing procedures, to

regularly monitor the care provided by clinic staff to assure that the quality of that care meets the established criteria;

3. To provide constructive feedback and education to audited staff in order to correct deficiencies and upgrade skills;
4. To keep all staff continually informed of expected standards for all aspects of care;
5. To continually update the clinic's standards of care to ensure they accurately address the needs of the patient population;
6. To detect and correct any deficiency in clinic structure, equipment, policy, or function that prevents patient care from meeting the established criteria.
7. To achieve consistent excellence in patient care and in its overall contribution to disease intervention. (See Appendix A for an example of a Quality Assurance Program).

Standards

- Each STD clinic has a quality assurance procedure in place which should include:
  - The periodic (monthly) auditing of medical records, usually by a QA committee comprised of the clinic manager, the quality assurance coordinator (an outside objective individual selected to review records, present findings, and coordinate QA committee responses), and representatives from the health department and all clinic staff positions, including the D.I.S. (Records should be assessed against the clinic protocol to determine both the appropriateness of diagnosis and treatment as well as for compliance with completion of the medical record);
  - Regular monitoring (at least every 6 months) by direct observation of clinic staff performance during interactions with patients (see Appendices H: "Clinician Evaluation Form", and I: "Registration Clerk Evaluation Form");
  - Regular monitoring of the quality of stat lab procedures, such as Gram stain/culture correlation of male urethral discharges, etc;
  - Evaluating problem areas recognized by staff;
  - Evaluating significant complaints of, or satisfaction of patients.

PART II

MEDICAL PROTOCOLS

INTRODUCTION TO STD MEDICAL PROTOCOLS

Although it is impossible to reach complete agreement on the optimal diagnostic criteria and management for each STD, clinics should have disease specific protocols to guide their STD clinicians. STDs are, for the most part, amenable to standard diagnostic procedures and treatment regimens. Protocols establish expectations for activities of physicians, nurse practitioners, physician assistants, and other clinicians; and form the basis for evaluating the quality of care in the clinic.

This section contains protocols for a number of STDs divided into groups. The protocols for the management of patients with STD are based on those formally designed by CDC and reviewed by others.

The STD considered here are listed below. The order of appearance of diseases within each group does not imply their relative importance.

Common STDs that all clinics diagnose, actively investigate, treat, and followup include:

- Gonococcal Infections: Uncomplicated, Penicillinase-producing *Neisseria gonorrhoeae* (PPNG), Chromosomally Mediated Resistant *N. gonorrhoeae* (CMRNG)
- *Chlamydia Trachomatis* Syndromes:
  - — Nongonococcal urethritis
  - — Acute Epididymo-orchitis
  - — Mucopurulent Cervicitis
  - — Pelvic Inflammatory Disease (PID)
- Vulvovaginitis
- Syphilis: Early, Late, Congenital

Important viral infections for which sexual transmission is prominent and for which investigators are actively seeking effective methods for prevention and treatment:

- Cytomegalovirus infections
- Hepatitis B virus infections
- Herpes simplex virus infections
- Human papilloma virus infections
- Acquired Immunodeficiency Syndrome (AIDS), AIDS Related Conditions (ARC), and Human T-Lymphotrophic Virus Type-III (HTLV-III) infections

Uncommon STDs for which specific antibiotic therapy is readily available:

- Chancroid
- Granuloma inguinale
- Lymphogranuloma venereum

Treatable sexually transmissible conditions which are not major threats to public health but may be very disturbing to individuals:

- Pediculosis
- Scabies
- Molluscum contagiosum
- Yeast infection

Some STD clinics see patients with enteric infections. This group of infections may be transmitted sexually or nonsexually through fecal-oral contamination. Specific sexual practices, particularly oral-anal contact, increases the risk of these infections. Diagnostic procedures and specific treatments are available for most of these infections:

- Amebiasis
- Campylobacter-associated enteritis
- Giardiasis
- Hepatitis A virus infections
- Salmonellosis (including typhoid fever)
- Shigellosis

Each disease protocol includes sections on diagnosis, treatment, followup, and evaluation of sex partners. Criteria are listed for several possible levels of certainty for each diagnosis: definitive, presumptive, and suggestive. Meeting the criteria for a definitive diagnosis represents the highest level of confidence. A presumptive diagnosis, while not definitive, reflects a sufficient level of confidence to warrant full treatment and followup. **Suggestive criteria do not confirm the diagnosis but are useful in patient management. Here, the potential benefit of treatment must be weighed against the risk of withholding or delaying it. Whenever a suggestive diagnosis is made, the clinician should attempt to obtain laboratory evidence to support a definitive diagnosis.**

Patient education and counseling are crucial in the management of all STDs. Since each already has been covered in this QAG, they will not be specifically included in these protocols unless special considerations deserve emphasis.

ACQUIRED IMMUNODEFICIENCY SYNDROME

Acquired immunodeficiency syndrome (AIDS) is part of the clinical spectrum of disease associated with human T-lymphotropic virus type-III/lymphadenopathy-associated virus (HTLV III/LAV) infection. The clinical conditions associated with HTLV-III/LAV infection may be a direct consequence of infection with this virus or a secondary condition

occurring as a consequence of the immune dysfunction caused by the underlying viral infection. The known clinical manifestations of disease associated with this infection include asymptomatic carriage of the virus, generalized lymphadenopathy, as well as the severe and possibly life-threatening illnesses which characterize the clinical syndrome of AIDS. Other non- life threatening fungal, viral, and bacterial infections may be associated with HTLV-III/LAV infection because of the underlying immunologic abnormalities.

Current laboratory test for antibody to HTLV-III/LAV make it possible to identify individuals who have been infected with this virus and who have developed antibody. Current data suggest that persons with antibody may be infected, may remain infected indefinitely, and be infectious continually or intermittently. Viral antigen detection techniques, which detect actual parts of the virus rather than antibody, are not yet available.

Among individuals with antibody to the HTLV-III/LAV, the risk of developing the frank clinical syndrome of AIDS is unknown. Preliminary estimates from cohorts of homosexual men followed prospectively for 2 to 5 years indicate that between 5 percent and 20 percent of individuals with confirmed detectable antibodies to HTLV-III/LAV may go on to develop the clinical syndrome of AIDS. Another 25% of these individuals may develop generalized lymphadenopathy or other AIDS related conditions. Likewise, the risk of these patients progressing to the clinical syndrome of AIDS is unknown. Therapeutic interventions that specifically eradicate the virus or reverse the immune dysfunction associated with this virus do not yet exist. Accordingly, prevention of primary viral infection is of paramount importance.

Long-term follow-up and care of patients with HTLV-III/LAV infections is complicated and beyond the scope of care delivered in STD clinics. Patients with HTLV-III/LAV infections should be referred to health care providers identified as consultants for these patients. **However, clinicians in STD clinics should be able to recognize patients with symptoms or signs suggestive of HTLV-III/LAV infection, because the patients seen in these clinics are at increased risk for exposure to sexually transmitted infections. Prompt recognition and referral will help provide better care and follow-up for the patient and help to control transmission of infection.**

Approach to Evaluation

Clearly, careful evaluation of individuals at increased risk for HTLV-III/LAV infection is important. Currently, men with sexual partners of the same sex, intravenous drug abusers, people with hemophilia, and patients infected through transfusion of blood or blood products comprise well over 90 percent of the reported cases of AIDS. Individuals in those characteristics and their sexual partners are at increased risk for HTLV-III infection.

Certain aspects of the patient's medical history, as well as findings on physical examination, may help the clinician recognize the possibility of HTLV-III/LAV infection. Several relevant areas are described below.

General Medical History - With individuals suspected to have HTLV-III/LAV infection, the clinician should review possible sources of infection such as identifying known risk factors or exposures which may increase the chance of infection, e.g., IV drug abuse, prior blood transfusions, prior acupuncture, tattoos, and needlestick injuries. Constitutional symptoms, particularly the presence of recurring or persistent fevers, night sweats, easily induced fatigue, involuntary weight loss, depressed appetite, chronic unexplained diarrhea, as well as symptoms associated with depression such as decreased libido, withdrawal behavior, and changes in sleeping patterns, are frequently reported by patients with HTLV-III/LAV infection.

Sexual History - Reviewing sexual orientation and a history of sexual practices may provide addition useful information. However, local and State legal statutes concerning the confidentiality of the medical record vary. Every effort should be made by the clinical staff to understand these statutes in their area. Sensitive information should not be recorded on the medical record unless the confidentiality of this record is protected by local laws.

Skin - Kaposi's sarcoma (KS) is a type of neoplasm frequently seen in patients with AIDS. KS is characterized by reddish purple nodules on the skin. In addition to the skin, these lesions may be seen on both oral and rectal mucosal surfaces as well. Other skin conditions conditions suggestive of impairment of the immune system may be associated with HTLV-III/LAV infection. Such lesions include herpes simplex and zoster infections, seborrheic dermatitis, unexplained diffuse hyperpigmentation and alopecia.

Oral Candida infections may occur and in some cases precede opportunistic infections. A unique lesion known as oral hairy leukoplakia (HL) can be an initial manifestation of AIDS. HL of the tongue apppears as raised white areas of thickening on the tongue, usually on the lateral border. Candida has been reported on the surface of HL lesions.

Lymph Nodes - Generalized lymphadenopathy is a frequent and consistent finding in patients with HTLV-III/LAV infection. The cervical, supraclavicular, axillary, epitrochlear, and inguinal areas should be examined.

Respiratory - Cough and/or shortness of breath may be the only findings in patients with *Pneumocystis* pneumonia, an opportunistic infection frequently seen in patients with AIDS.

Gastrointestinal (GI) - Opportunistic infections seen in patients with HTLV-III/LAV infection may frequently involve the gastrointestinal tract. Candida esophagitis may present as difficult or painful swallowing. Watery diarrhea may occur as a result of protozoan infections of the lower GI tract.

Musculosketal - Diffuse arthralgias and myalgias can be associated with the febrile prodrome sometimes seen in patients with HTLV-III infection.

Laboratory evaluation

Laboratory tests which may be helpful in evaluating individuals with suspected HTLV-III/LAV infection include the HTLV-III antibody test, a complete blood count with differential, skin tests with recall antigens, and immunogobulin electropheresis. AIDS patients tend to have positive HTLV-III antibody tests, leukopenia (mainly lymphopenia) and elevated immunoglobulins (particularly IgG). Additional specific tests should be directed by the clinical findings.

Primary Prevention

Prevention of infection is the only effective control measure currently available for AIDS. As of yet, no specific therapeutic interventions have been shown to reverse the immunodeficiency associated with infection or to eradicate the infection. In populations known to be at increased risk for infection through sexual transmission, health professionals should encourage individuals to change their sexual practices to decrease their risk of exposure to the virus as well as to decrease the risk of transmission. Although the risk of transmission of HTLV-III/LAV may vary with sexual practices, the most important risk factor in virtually all epidemiologic studies is an increased number of sex partners.

HTLV-III/LAV has been identified in the semen, saliva, and blood. Therefore, any exchange of semen, blood, or other bodily secretions, or excretion with an infected person at least theoretically could result in infection with HTLV-III/LAV. No sexual activity with individuals who are infected can be excluded as a possible means of transmission.

The following interim guidelines are recommended until further information becomes available, or other effective primary or secondary prevention methods are developed.

1. The only certain method to prevent transmission or acquisition of infection is abstention from all sexual intercourse with persons infected with HTLV-III/LAV. Permanent, monogamous sexual relationships introduce no new risk for infection provided neither partner is currently infected and both partners have no other sex partners outside of the relationship. Sexual contact with multiple partners or with individuals with large numbers of casual partners greatly increases the risk of acquiring this infection, as well as other sexually transmitted infections.
2. Individuals who choose to continue to have multiple sex partners or to initiate new relationships with individuals at increased risk for HTLV-III/LAV infection should make a specific effort to limit the exchange of bodily secretions or blood during sexual activity. Strong efforts should be made to avoid contact of mucous membranes with blood, semen, pre-ejaculate secretions, vaginal secretions, saliva, tears, urine, and feces. Fisting is strongly discouraged. Condoms are recommended for all sexual activity that could possibly result in ejaculation.
3. Parenteral use of illegal drugs should be avoided. The sharing of needles and the use of unsterilized needles should also be avoided.
4. Nitrite inhalents ("poppers") may be implicated as a cofactor for Kaposi's sarcoma and should be avoided.
5. Any man who has had sex with another man since 1977 should not donote blood or plasma. This applies even to men who may have only a single contact and who do not consider themselves homosexual or bisexual should refrain from donating blood, plasma, semen or organs for transplant. Members of other groups at increased risk for HTLV-III infection should also refrain from donating blood.

A directed medical and social history, as well as a directed physical examination is recommended for individuals with signs or symptoms suggestive of HTLV-III/LAV infection. Prompt referral for in-depth evaluation is necessary for patients with suspected HTLV-III/LAV infection.

ACUTE EPIDIDYMO-ORCHITIS

This condition can be divided into a sexually transmitted form frequently associated with urethritis and commonly caused by *C. trachomatis* and/or *N. gonorrhoeae* and a non-sexually transmitted form associated with urinary tract infections. Urine should be examined by gram stain and culture to exclude bacteruria in all patients, including those with urethritis. Testicular torsion is a surgical emergency which should be considered in all cases.

A. Acute Epididymo-Orchitis in Heterosexual Men Less than 35 Years of Age

1. Drug Regimen of Choice

This form of epididymo-orchitis occurs in young adults and is associated with urethritis, absence of underlying genitourinary pathology and absence of gram negative rods on gram stain of urine.

Amoxocillin 3.0 gm by mouth, or
Ampicillin 3.5 gm by mouth, or
Aqueous procaine penicillin 4.8 million units (each along with probenecid 1.0 gm by mouth), or
Spectinomycin 2.0 gm IM, or
Ceftriaxone 250 mg IM
followed by
Tetracycline HCl, 500 mg by mouth, 4 times a day, for at least 10 days;

OR

Doxycycline, 100 mg by mouth, twice a day, for at least 10 days.

OR

(For patients for whom tetracyclines are contrain-

dicated or not tolerated) Erythromycin base a 500 mg by mouth 4 times a day for 7 days, or
erythromycin ethyl succinate 800 mg by mouth 4 times a day for 7 days.
Erythromycin stearate 500 mg by mouth 4 times daily for 7 days may also be effective.

2. **Adjuncts to Therapy**
Bed rest, scrotal elevation until fever and local inflammation have subsided are recommended.

3. **Followup**
Failure to improve within 3 days requires reevaluation of diagnosis/therapy and consideration for hospitalization. Persistence of swelling for longer than one month should be evaluated.

4. **Evaluation of Sex Partners**
Sex partners of patients with sexually transmitted acute epididymo- orchitis should be examined for other STD and promptly treated with a regimen effective against uncomplicated gonococcal and chlamydial infection.

B. Acute Epididymo-Orchitis in Men Over 35 Years of Age

Management includes prompt administration of broad spectrum antimicrobial therapy. Choice of therapy is initially dictated by the severity of infection and later by results of urine culture and sensitivity. Evaluation for underlying urinary tract disease is indicated. Adjuncts to Therapy and Followup are the same as for sexually transmitted acute epididymo-orchitis.

CHANCROID

Since many STDs cause genital ulcers, it is crucial to differentiate among them. All ulcers should be examined with darkfield microscopy. Genital ulcers seen in patients with chancroid are usually painful.

A. Diagnosis

1. The diagnosis of chancroid is definitive when a culture is positive for *Haemophilus ducreyi*.

2. The diagnosis is presumptive when organisms morphologically consistent with *H. ducreyi* are found on a smear of bubo aspirate, or lesions reveal organisms resembling *H. ducreyi* in chains or clumps along strands of mucus.

3. The clinical presentation of chancroid involving the genitalia with or without a unilateral bubo suggests the diagnosis, if the darkfield exam is negative and other causes of ulcers, such as herpes simplex and lymphogranuloma venereum, are excluded.

B. Treatment

Erythromycin, 500 mg by mouth, 4 times a day for 7 days; OR Ceftriaxone, 250 mg, IM in a single dose.

C. Lesion Management

Fluctuant lymph nodes should be aspirated through healthy adjacent normal skin to prevent spontaneous rupture and drainage. Incision and drainage or excision of nodes will delay healing and should be avoided.

Applying warm compresses to ulcers will help remove necrotic material and give some symptomatic relief.

D. Followup

Followup schedules are individualized, but should be at no longer than weekly intervals until the lesion(s) are clearly resolving. Followup should continue until complete resolution has occurred. Patients should understand the importance of abstaining from sex while any lesion is present.

E. Evaluation of Sex Partners

Current sex partners should receive a routine STD evaluation and be treated with a regimen adequate for uncomplicated chancroid.

NOTE: Antimicrobial susceptibility testing should be performed on *H. ducreyi* isolated from patients who do not respond to the recommended therapies.

CHLAMYDIA TRACHOMATIS INFECTIONS

Infections caused by *Chlamydia trachomatis* are one of the most prevalent sexually transmitted diseases in the United States today. The importance of serious complications related to chlamydial infections has been established. Diagnosis and treatment of these infections are frequently based on the clinical syndrome since chlamydial tests often are unavailable. The following guidelines are for *culture-proven* infections caused by non-LGV strains of *C. trachomatis*. For approaches to the treatment of common chlamydial infections when cultures are not available, see the sections on "PID," "Nongonococcal Urethritis," "Epididymo-orchitis," and "Mucopurulent Cervicitis in Women."

A. Adults

For uncomplicated urethral, endocervical, or rectal infection.

1. **Drug Regimens of Choice**
Tetracycline hydrochloride (HCl), 500 mg by mouth, 4 times a day, for at least 7 days; OR
Doxycycline 100 mg by mouth, twice a day, for at least 7 days.

2. **Alternative Regimens (For patients in whom tetracyclines are contraindicated or not tolerated.)**
Erythromycin base, 500 mg by mouth, 4 times a day, for 7 days,
OR
Erythromycin ethyl succinate 800 mg by mouth, 4 times a day for 7 days.
Erythromycin sterate in the same dose as the base may also be effective

Sulfonamides are also active against *C. trachomatis*, but have not been extensively studied.

3. **Evaluation of Sex Partners**
   All persons exposed to *C. trachomatis* infection should be examined for STD and promptly treated for *C. trachomatis* with one of the above regimens.

4. **Followup**
   When taken as directed, the tetracycline and erythromycin regimens listed are highly effective. Therefore, posttreatment cultures may not be necessary if resources are limited. Positive cultures may not be detectable until 3-6 weeks posttreatment; when they are positive, patients should be retreated with one of the above regimens.

B. Chlamydial Urogenital Infections During Pregnancy

Treatment should be given to women who have infections established by culture of *C. trachomatis* or if cultures are not available, to those women whose sex partners have nongonococcal urethritis.

The suggested treatment is erythromycin base, 500 mg by mouth, 4 times a day on an empty stomach for at least 7 days or erythromycin ethylsuccinate, 800 mg by mouth, 4 times a day for 7 days. Erythormycin sterate in the same dose as the base may also be effective. In women who cannot tolerate this regimen, a decreased dose of 250 mg by mouth, 4 times a day, should be used for at least 14 days. The optimal dose and duration of antibiotic therapy for pregnant women has not been established. There are presently no completely acceptable alternative regimens for women who are allergic to erythromycin or cannot tolerate this antibiotic. Proven treatment failures should be retreated with erythromycin in either of the dosage schedules outlined above.

Treatment of the male partner(s) with tetracycline at the same time is an important part of the therapeutic regimen.

Chlamydial cultures are expensive and not widely available. Pregnant women at particular risk for chlamydial infections should have cultures taken if possible at their first prenatal visit. In general, infecton has been most prevalent in unmarried women, women less than 20, and residents of lower socioeconomic, inner-city communities. Rates of infection are also high in women with nongonococcal mucopurulent cervicitis, women who are sexual partners of men with nongonococcal urethritis and women reporting late for prenatal care.

C. Established Chlamydial Conjunctivitis of the Newborn

For all cases of ophthalmia neonatorum, appropriate tests should be done to rule out *Neisseria gonorrhoeae* as the cause.

The diagnosis of chlamydial conjunctivitis can be established by culture or Giemsa-stained conjunctival scrapings. Treatment consists of oral erythromycin syrup 50 mg/kg/day in 4 divided doses for at least 2 weeks. There is no indication that topical therapy provides additional benefit. If inclusion conjunctivitis recurs after stopping therapy, erythromycin treatment should be reinstituted for an additional 1 to 2 weeks.

D. Chlamydial Pneumonia of Infancy

For established cases of lower respiratory disease due to *C. trachomatis* the recommended therapy is oral erythromycin syrup, 50 mg/kg/day in 4 divided doses for at least 14 days. The optimal duration for therapy has not been established.

CYTOMEGALOVIRUS (CMV) INFECTION

A. Diagnosis

Many healthy individuals shed CMV in their saliva, cervical secretions, urine, semen, breast milk, feces, or blood. Clinical manifestations of acquired CMV infection may include pneumonia, mononucleosis syndrome, hemolytic anemia, splenomegaly, and petechial rash, but frequently no clinical symptoms are observed. The most frequent manifestations of congenital illness are hepatosplenomegaly, jaundice, purpura, microcephaly, cerebral calcifications, and choreoretinitis. A major sequela of congenital CMV infection is deafness. Less specific findings in newborns are failure to thrive and recurrent respiratory infections.

1. Definitive diagnosis requires that the virus be identified in cell culture by cytopathogenic effect (CPE) or by immunofluorescence AND that clinical illness be present.
2. A presumptive diagnosis is made when a (4 fold rise in CMV titer in paired acute and convalescent sera is detected by the complement fixation (CF) test AND clinical illness is present. Symptomatic contacts of definitively or presumptively diagnosed CMV patients may be presumed to have CMV infection as well.

B. Treatment

Treatment is supportive, nonspecific, and symptomatic. Sexual abstinence or use of condoms are indicated when clinical infection is present.

C. Followup

Followup schedules are individualized according to clinical progress. The acquired illness is usually self-limited among immunocompetent individuals.

D. Evaluation of Sex Partners

Sex partners should be offered an STD evaluation. Presently, there is no specific therapy or vaccine to offer sex partners of patients with CMV infection.

ENTERIC INFECTIONS

A comprehensive review of the diagnosis and treatment of the sexually transmitted enteric infections is beyond the scope of this document. However, awareness of the sexual transmission of these infections is crucial to the understanding of their epidemiology.

The sexually transmissible enteric pathogens include protozoa such as *Entamoeba histolytica* (amebiasis) and *Giardia lamblia* (giardiasis); viruses such as hepatitis A virus; and bacteria such as *Shigella sp, Campylobacter jejuni*, and *Salmonella sp* (bacterial dysentery or enteritis).

Because the field of enteric infections is large and complex, referring to the current medical literature is most important. The CDC provides consultation on enteric infections through the Bacterial Diseases, Parasitic Diseases, and Hepatitis and Viral Enteritis Divisions of the Center for Infectious Diseases as well as through the Division of Sexually Transmitted Diseases of the Center for Prevention Services.

A. Diagnosis

Definitive diagnoses depend upon specific identification of organisms. In some illnesses this is easy to accomplish. For instance, shigellosis and salmonellosis can be diagnosed by culturing a fresh stool specimen. Protozoa and helminths can be diagnosed by direct identification of ova, cysts, or trophozoites on microscopic examination, but a series of such examinations may be necessary. For some infections, a definitive diagnosis may be difficult to establish. For instance, *Campylobacter sp* requires a specific culture medium and temperature. Definitive tests for hepatitis A are not generally available. This diagnosis is usually a clinical one, supported by the exclusion of hepatitis B (and other forms of hepatitis).

B. Treatment

Treatment of proctitis and enterocolitis should be based on etiologic diagnosis. Appropriate gastroenterologic workup should be pursued in all cases. *Asymptomatic, infected individuals for whom anal-oral contact is a sexual practice should be treated in accordance with recommendations for symptomatic individuals*, as should persons whose work or social situation is associated with a likelihood of transmission (e.g., food handlers, hospital workers, day care center employees, etc.). Sex partners at risk for fecal-oral transmission should be evaluated for enteric infections and other STD. Sexual transmission does not preclude the possibility of non- sexual transmission as well. Careful attention to handwashing and other hygenic practices is strongly urged.

1. Campylobacter Jejuni

The drug of choice for symptomatic enterocolitis or proctitis is:

Erythromycin, 500 mg by mouth, 4 times a day, for 7 days.

2. Shigella Species

Antibiotic choice must be based on the sensitivity pattern of the isolate. Immediate treatment, when required, may be based on local sensitivity patterns. Current national sensitivity patterns suggest that the drug of choice is:

Trimethoprim/Sulfamethoxazole (160/800 mg) by mouth, twice daily for 7 days.

An alternative is ampicillin, 500 mg by mouth, 4 times daily, for 7 days, though the variability of regional sensitivity of shigellae to ampicillin must be considered. Amoxicillin is **not** an acceptable substitute.

3. Nontyphoidal Salmonella Species

Treatment of asymptomatic carriage or uncomplicated symptomatic infection is not generally recommended. Sex partners should be evaluated.

4. Amebiasis

Laboratory diagnosis may be complicated by prior use of antidiarrheal agents and antibiotics such as tetracyclines or erythromycin. In symptomatic patients the regimen of choice consists of a systemic drug plus a lumenal amebicide:

Metronidazole, 750 mg by mouth, 3 times daily, for 5-10 days,

PLUS

Iodoquinol (Diiodohydroxyquin), 650 mg by mouth, 3 times daily, for 20 days; OR
(Diloxanide furoate, 500 mg by mouth, 3 times a day, for 10 days is also effective but is available from CDC only for asymptomatic cyst passers.)

NOTE: A second choice regimen is metronidazole alone, followed sequentially by one of the lumenal amebicides if clinical cure is not achieved.

The regimen of third choice is:

Paromomycin*, 25-30 mg/kg/day, in 3 divided doses, for 7 days.

This drug is used alone. Though primarily a lumenal amebicide, it has been noted to have superficial tissue effect.

For asymptomatic amebic cyst passers, the lumenal amebicides alone are sufficient (iodoquinol 650 mg, by mouth, 3 times a day, for 20 days; or diloxanide furoate, 500 mg by mouth, 3 times a day, for 10 days). Severe disease or extraintestinal illness should prompt appropriate medical consultation and referral.

5. Giardiasis

a. Drug Regimen of Choice

Quinacrine, 100 mg by mouth, 3 times daily, for 7 days.

b. Alternative Therapy:

Metronidazole, 250 mg by mouth, 3 times a day, for 7 days. In the case of coexistent symptomatic amebiasis and giardiasis, metronidazole in the higher dose may be preferred.

As with other protozoal pathogens, initial treatment of asymptomatic carriers is indicated. Retreatment of recurrences, either from relapse or reinfection, depends on individual and epidemiologic circumstances.

* available through CDC.

NOTE: Chlamydial and gonococcal rectal infections are discussed in the sections dealing with those organisms. Presently, there is no specific treatment for proctitis associated with herpes simplex virus infection.

C. Followup

1. All patients with enteric infection should be educated about the modes of transmission of these pathogens and encouraged to modify or at least temporarily curtail behaviors which place them at risk for reinfection. As with all STDs, nonjudgemental attitudes are vital to therapeutic success.

2. Following a course of therapy, several stool specimens should be examined for pathogens before cure can be reasonably well established. It may be difficult to distinguish reinfection from treatment failures. Additional therapy, educational efforts to modify sexual practices, and followup are indicated.

D. Evaluation of Sex Partners

Sex partners should be screened for STDs and any enteric pathogens to which they are exposed.

GENITAL HERPES SIMPLEX VIRUS INFECTIONS

A. Diagnosis

1. A definitive diagnosis is made when a herpes simplex virus (HSV) is isolated and identified in cell culture from scrapings taken from the cervix, the urethra, or the base of a genital lesion.

2. A presumptive diagnosis requires that a specimen from a genital lesion demonstrate:

   a. Multinucleated giant cells with intranuclear inclusions by Pap or other histochemical stain; or
   b. Typical HSV morphology by electron microscopy; or
   c. HSV by direct immunofluorescence or immunoperoxidase tests such as enzyme-linked immunosorbent assays is not currently recommended because of false positive results.

NOTE: Immunoassays may detect biologically inactive or defective particles.

An increasing antibody titer in the herpes complement fixation (HSV-CFT) or other HSV serologic tests between acute and convalescent sera further supports a presumptive diagnosis.

3. Herpes genitalis is suspected whenever darkfield negative, typical, herpetic, genital lesions are present or a pattern of recurrence has developed.

B. Treatment

Genital herpes infection is a viral disease which may be chronic and recurring and for which there is no known cure. However, acyclovir may provide partial control of the signs and symptoms associated with genital herpes; but this does not affect the subsequent risk, frequency, or severity of recurrences after the drug is discontinued.

1. First Clinical Episode

Clinicians may elect to use acyclovir to reduce the signs and symptoms:

Acyclovir 200 mg by mouth 5 times daily for 7-10 days, initiated within 6 days of the onset of lesions.

This treatment shortens the median duration of first episode eruptions by 3 to 5 days and may reduce systemic symptoms in primary episodes.

Topical acyclovir ointment has marginal benefit in decreasing virus shedding, but has no significant effect on symptoms or healing time.

Acyclovir has not been tested in pregnant or lactating women.

2. Recurring Disease Treatment

Since benefit to the patient may be minimal, treatment of recurrent episodes with acyclovir should be limited to those patients who typically have severe symptoms and who are able to begin therapy at the beginning of the prodrome or within 2 days of the onset of lesions.

3. Obstetrical and Perinatal Management

The management of obstetrical and perinatal herpes simplex viral infections, as recommended by the Committee of Fetus and Newborn and the Committee on Infectious Diseases of the American Academy of Pediatrics, appears in Appendix K.

C. Patient Counseling

Patients should be told about the natural history of genital herpes infection and to abstain from sexual contact while lesions are present. The risk of transmission of the herpes virus during asymptomatic periods is unknown. Some consultants recommend that asymptomatic patients use condoms, but their efficacy is unproved. Women with genital herpes infection should be advised to have yearly Pap smears. Early in pregnancy, women should inform their clinician of their history of genital herpes infection.

D. Followup

Followup schedules are individualized according to clinical progress. Complete resolution of lesions without scarring is expected.

E. Evaluation of Sex Partners

Sex partners should be offered a routine STD evaluation. Presently, there is no specific therapy or vaccine to offer sex partners of patients with genital herpes.

GONOCOCCAL INFECTIONS

A. Diagnosis

- **Criteria for uncomplicated urethritis, endocervicitis, proctitis and pharyngitis.**

1. Definitive culture diagnosis is the same for all ages, sex groups and sites. It must include typical colonial morphology on selective culture medium, typical Gram stain morphology, positive oxidase reaction, and a positive confirmatory test, such as sugar utilization, coagglutination, or antigonococcal fluorescent antibody testing.
2. Presumptive culture diagnosis applies only to adult anorectal and genitourinary sites. It must include typical colonial morphology on selective culture medium, typical gram stain morphology, and positive oxidase reaction.
3. Presumptive smear diagnosis applies only to adult males with urethral discharge and, depending on the expertise of the clinic laboratory, adult female endocervical smears. It must include typical Gram-negative intracellular diplococci on Gram stain smear, read by well trained personnel.
4. Suggestive diagnosis includes epidemiologic, clinical, and other laboratory evidence of gonorrhea.

TABLE 3. Summary of the Minimum Laboratory Evidence Required to Initiate Treatment and Sex Partner Followup for Uncomplicated Gonorrhea

	Sampling Site		
Population	Genitourinary	Anorectal	Extragenital
Adult Male	3*	2	1
Adult Female	2-3**	2	1
Children	1	1	1

* **The numbers in Table 3 refer to the categories of diagnostic criteria above.**

** Although a positive endocervical smear can be specific for a presumptive diagnosis, the test is so insensitive, that a culture is required whenever a smear is done.

- **Criteria for antibiotic-resistant N. gonorrhoeae.**

Infections caused by resistant organisms such as penicillinase-producing *N. gonorrhoeae* (PPNG) and spectinomycin-resistant *N. gonorrhoeae* are clinically indistinguishable from those caused by susceptible strains.

Because of the recent increases in recognized PPNG infections and because early detection makes intervention efforts more effective, CDC now strongly advises that all laboratories consider intensifying their surveillance programs for detection of PPNG strains. The first step is laboratory testing of all gonococcal isolates for β-lactamase production. In areas with outbreaks of PPNG infections, surveillance can be further intensified by culturing urethral specimens from men with urethritis (if such cultures are not done routinely) and then testing all positive cultures for β-lactamase production.

Spectinomycin-resistant *N. gonorrhoeae* have been reported, including spectinomycin-resistant PPNG. CDC now recommends that all PPNG isolates be tested for spectinomycin resistance using a provisional disc-diffusion method. A protocol for this method is available from either State laboratories or CDC.

1. Definitive diagnosis of PPNG requires a definitive culture diagnosis for *N. gonorrhoeae* plus documented β-lactamase production in a pure culture according to a specific test such as the iodometric, the acidometric, or the chromogenic cephalosporin test. (Note that these tests are specific for β-lactamase, but not for *N. gonorrhoeae*. Many other bacteria are capable of producing the enyzme.)
2. Presumptive laboratory diagnosis of PPNG is reached when any β-lactamase test of a primary isolate of *N. gonorrhoeae* of uncertain purity is positive.
3. Presumptive clinical diagnosis of PPNG is reached when:
   a. A patient presumed to have gonorrhea (see previous section) has a sex partner with definitive or presumptive PPNG.
   b. A patient presumed to have gonorrhea has recently traveled to a locality where PPNG is highly prevalent.
4. Suggestive diagnosis of PPNG is reached when:
   a. Any gonorrhea patient treated with an adequate dose of penicillin fails to be cured.
   b. The patient meets the criteria suggestive of uncomplicated gonorrhea and has a sex partner with definitive or presumptive PPNG or history of recent travel to a country where PPNG is highly prevalent.

- **Criteria for Disseminated Gonococcal Infection (DGI).**

1. The diagnosis of DGI depends primarily on physical findings. Many patients will have negative cultures. Definitive and presumptive culture diagnoses are identical to those for uncomplicated gonococcal infections and depend on isolation of the organism except for the sites of infection. In DGI, the organism may be recovered from the blood or a site not likely to have been infected initially.
2. Presumptive smear diagnosis applies to patients with clinical septicemia or evidence of dissemination and typical gram negative diplococci on gram stain smear taken from a site not likely to have been infected initially or through direct spread from the initial site.
3. Suggestive diagnosis applies to patients with clinical septicemia or evidence of dissemination who meet the criteria for definitive, presumptive, or suggestive diagnosis of uncomplicated gonorrhea. The physician should consider DGI in any patient presenting with tenosynovitis, oliganthritis, or unexplained pustular skin lesions.

B. Treatment

The following guidelines for the treatment of gonococcal infection in the United States take into account several observations: the high frequency of coexisting chlamydial and gonococcal infections; increased recognition of the serious complications of chlamydial and gonococcal infections; the difficulty in diagnosing chlamydial infections; the increasing incidence of infections due to (PPNG); and reports of the emergence of tetracycline resistant gonococci in several geographic areas. In addition, new antimicrobials which may prove to be effective in treating both gonococcal infection and coexisting chlamydial infections are becoming available in the U.S. Therefore, these guidelines do not attempt to be a comprehensive list of all possible treatment regimens. Rather, they seek to provide guidance for regimens which meet general criteria of efficacy, safety, ease of administration and cost.

1. Uncomplicated Infection in Adults

a. Therapy

An important concern in the treatment of gonorrhea is coexisting chlamydial infections, documented in up to 45 percent of gonorrhea cases when chlamydia culture is performed. Concern also exists about patient compliance with multiple day tetracycline/doxycycline regimens for gonococcal infections and for potential selection of tetracycline resistant isolates when incomplete doses are taken. To address the concerns, a single dose regimen for gonorrhea should be administered just prior to beginning a tetracycline or doxycycline regimen.

Amoxicillin 3.0 gm or ampicillin 3.5 gm by mouth or aqueous procaine penicillin G 4.8 million units IM; The above regimen should be accompanied by probenecid 1 gm by mouth. Ceftriaxone 250 mg IM.

PLUS

Tetracycline HCL 500 mg by mouth 4 times daily for 7 days or doxycycline 100 mg by mouth twice daily for 7 days.

OR

For patients in whom tetracyclines are contraindicated or not tolerated, the single dose regimen may be followed by erythromycin base 500 mg by mouth 4 times daily or by erythromycin ethylsuccinate 800 mg by mouth 4 times daily for 7 days. Erythromycin serate in the same dose as the base may be effective

Advantages	Disadvantages
1) Provides adequate single dose treatment for gonorrhea	1) Efficacy and side effects of this specific combined regimen have not been evaluated
2) Effective against chlamydial infections	2) The risk of secondary vulvo-vaginal candidiasis in women probably is enhanced
3) Effective against pharyngeal gonococcal infections	3) Test of cure cultures for gonorrhea must be delayed until 3 or 4 days after the completion of dual therapy
	4) Unknown potential for selection of resistant strains of *C. trachomatis* if compliance is poor
	5) Unknown potential for masking *C. trachomatis* infections in those who only partially comply with treatment

In women with rectal infection the above regimens are effective.

Rectal gonorrhea in men should be treated with ceftriaxone 250 mg IM or aqueous procaine penicillin G, 4.8 million units plus 1.0 g of probenecid. For patients allergic to penicillin, use spectinomycin, 2.0 g IM, in a single injection. These regimens provide adequate treatment for urethral and anorectal gonococcal infection but spectinomycin is ineffective in the treatment of pharyngeal gonococcal infection. Homosexual men are less likely than heterosexual men to have coexistant chlamydial infections; therefore, routine addition of tetracycline or doxycycline treatment is not advised.

b. Other Considerations

Patients who are allergic to penicillins, cehpalosporins, or probenecid should be treated with oral tetracycline or doxycycline as above. Penicillin-allergic patients who cannot tolerate tetracyclines may be treated with spectinomycin, 2.0 g IM, in a single injection.

All patients treated for gonorrhea should have a serologic test for syphilis. Patients with incubating syphilis (seronegative, without clinical signs of syphilis) are likely to be cured by all the above regimens except spectinomycin alone.

Patients with gonorrhea who also have syphilis or are established sex partners of syphilis patients should be given additional treatment appropriate to the stage of syphilis as outlined under "SYPHILIS."

c. Treatment Failures

If gonorrhea persists after treatment with one of the non- spectinomycin regimens, the patient should be treated with 2.0 g of spectinomycin IM. (See PPNG infections below.) Recurrent gonococcal infections after treatment with the recommended schedules may be due to reinfection rather than treatment failure, and indicate a need for improved contact tracing and patient education. Since resistance is a cause of treatment failure, posttreatment isolates should be tested for antimicrobial susceptibility.

d. Not Recommended

Although long-acting forms of penicillin (such as benzathine penicillin G) are effective in the treatment of syphilis, they have *NO* place in the treatment of gonorrhea. Penicillin preparations and cephalosporins *not recommended* for the treatment of gonorrhea include: benzathine penicillin G, oral penicillin G, penicillin V, cloracillin, dicloracillin, cephradine, cephalothen, cephapirin, cefozolin, cephalexin, cefadroxil, and cefalor.

e. Followup

All gonorrhea patients, regardless of site(s) of infection, antibiotic susceptibility, or treatment used, need to return for test of cure culture(s) 3-7 days after completion of treatment. Cultures should be obtained from each infected site. Additionally, because of the high rate of spillage from the infected endocervix to the anal canal, women should have anal canal test of cure cultures.

Other considerations include:

1) Screening all test of cure *N. gonorrhoeae* isolates for antibiotic resistance.
2) Performing a urethral smear on men, in addition to the culture, if discharge is present or the patient complains of dysuria.
3) Repeating examinations and cultures in 4-6 weeks.

f. Evaluation of Sex Partners

1) The most productive time frames in which to find untreated infected sex partners are listed in Table 4.

TABLE 4. The Intervals of Greatest Likelihood for Finding Untreated Infected Sex Partners of Gonorrhea Patients

Patient	Examine and Treat Preventively All Sex Partners Exposed to the Patient During the:
Female with asymptomatic, uncomplicated or antibiotic resistant gonorrhea.	45 days prior to the patient's diagnosis.
Female with gonococcal PID or DGI.	60 days prior to the patient's initial clinical assessment.
Male with symptomatic, uncomplicated, or antibiotic resistant gonorrhea.	30 days prior to the patient's onset of symptoms.
Male with asymptomatic gonorrhea or DGI.	60 days prior to the patient's diagnosis.

2) All sex partners should come to the clinic for routine evaluation (see Medical Care Section II.C.1, 2, 3, 4). Each exposure site should be cultured or gram stain tested, as appropriate.
3) Sex partners should receive preventive treatment with one of the regimens which cover both gonococcal and chlamydial infections. As a minimum, the treatment for uncomplicated gonorrhea is indicated. Partners exposed to an antibiotic resistant strain of *N. gonorrhoeae* should be assumed to have the same strain.

2. Penicillanise-producing *Neisseria gonorrhoeae (PPNG)*

Patients with proven PPNG infection or who are likely to have acquired gonorrhea in areas of high PPNG prevalence and their sex partners should receive spectinomycin, 2.0 g IM or ceftriaxone 250 mg IM in a single injection. Tetracycline, doxycycline, or erythromycin should follow both regimens as noted above. Ceftriaxone 250 mg IM as a single injection or a daily single dose of nine tablets of trimethoprim/sulfamethoxazole (80 mg/400 mg) for 5 days should be used to treat pharyngeal gonococcal infection due to PPNG. Spectinomycin is ineffective in pharyngeal infections.

3. Chromosomally Mediated Resistant *Neisseria Gonorrhoeae*

Patients who fail standard treatment for gonorrhea or who have infection with penicillin resistant strains that do not produce-lactamase should be treated with spectinomycin 2 gm IM or ceftriaxone 250 mg IM.

4. Gonococcal Infections in Pregnancy

All pregnant women should have endocervical cultures for gonococci as an integral part of the prenatal care at the time of the first visit. A second culture and a test for *C. trachomatis* late in the third trimester should be obtained from women at increased risk of sexually transmitted infections.

Drug regimens of choice are amoxicillin, or ampicillin, each with probenecid as described in the Uncomplicated Infections Section. APPG 4.8 mu is also effective, but is less desirable because of associated pain and toxicity. Erythromycin in the dosage recommended under chlamydial infection should be added to complete the dual treatment regimen. Women who are allergic to penicillin or probenecid should be treated with spectinomycin, 2.0 g IM.

Refer to the sections on acute salpingitis and disseminated gonococcal infections for the treatment of these conditions during pregnancy. Tetracycline should not be used in pregnant women because of potential adverse effects for the fetus.

5. Disseminated Gonococcal Infection (DGI)

Hospitalization is indicated for patients suspected to have disseminated gonococcal infections.

Several acceptable treatment schedules for dessiminated gonococcal infection include the following:

Aqueous crystalline penicillin G, 10 million units intravenously (IV) per day until improvement occurs,

FOLLOWED BY

Amoxicillin or ampicillin, 0.5 g by mouth, 4 times a day, to complete at least 7 days of antibiotic treatment; OR Amoxicillin, 3.0 g, or ampicillin, 3.5 g, each with probenecid, 1.0 g by mouth, followed by amoxicillin, 0.5 g, or ampicillin, 0.5 g by mouth, 4 times a day, for at least 7 days; OR

Cefoxitin, 1.0 g, or cefotaxime, 0.5 g, either given 4 times a day IV, for at least 7 days (treatment of choice for disseminated infections caused by PPNG); OR ceftriaxone 1 gm IV once daily for 7 days.

Patients treated with the above regimens should be given an additional 7 days of tetracycline, doxycycline, or erythromycin as outlined above.
Patients allergic to penicillins or cephalosporins may be treated with tetracycline 500 mg by mouth 4 times daily for at least 7 days or doxycycline 100 mg twice daily for at least 7 days.

a. Special Considerations

Open drainage of joints other than the hip is not indicated. Intra-articular injection of antibiotics is unnecessary.

6. Gonococcal Ophthalmia in Adults

Patients should be hospitalized and treated with aqueous crystalline penicillin G, 10 million units IV daily for 5 days. For PPNG, use cefoxitin, 1.0 g, or cefotaxime, 500 mg IV, 4 times a day or ceftriaxone 1 gm IM daily. Irrigation of the eyes with saline or buffered ophthalmic solutions should be performed immediately and then at least at hourly intervals as long as necessary to eliminate discharge. Cases must have careful ophthalmic followup to deal with ocular complications.

7. Infants Born to Mothers with Gonococcal Infection

The infant born to a mother with gonorrhea is at high risk of infection and requires treatment with a single injection of aqueous crystalline penicillin G, 50,000 units IM or IV, to full-term infants; or 20,000 units IM or IV, to low-birth-weight infants. Topical prophylaxis for neonatal ophthalmia is not adequate treatment for infections at other sites. Clinical illness requires additional treatment.

8. Neonatal Gonococcal Infection

a. Gonococcal Ophthalmia

Patients should be hospitalized and isolated for 24 hours after initiation of treatment. Aqueous crystalline penicillin G, 100,000 units/kg/day IV, in 4 doses, should be administered for 7 days. Irrigation of the eyes with saline or buffered ophthalmic solutions may be useful adjunctive therapy to eliminate discharge. Topical antibiotic preparations alone are not sufficient and are not required when appropriate systemic antibiotic therapy is given. Both parents of newborns with gonococcal ophthalmia must be treated.

b. Penicillinase-producing Neisseria gonorrhoeae (PPNG)

Neonates should be treated with cefotaxime or gentamicin in appropriate neonatal doses.

c. Complicated Infection

Patients with arthritis and septicemia should be hospitalized and treated with aqueous crystalline penicillin G, 100,000 units/kg/day IV, in 4 divided doses, for at least 7 days. Meningitis should be treated with aqueous crystalline penicillin G, 100,000 units/kg/day IV, divided into 4 doses, and continued for at least 10 days.

9. Gonococcal Infections of Older Children

Children who weigh 100 lbs. (45 kg) or more should receive adult regimens. Children who weigh less than 100 lbs. should be treated as follows:

a. Uncomplicated Disease

Uncomplicated vulvovaginitis and urethritis: amoxicillin, 50 mg/kg orally with probenecid, 25 mg/kg (maximum 1.0 g); OR ceftriaxone 125 mg IM in a single injection. The latter regimen is recommended for proctitis and pharyngitis. Aqueous procaine penicillin G 100,000 units/kg IM plus probenecid 25 mg/kg (maximum 1.0 gm) by mouth is effective, but should be avoided because of associated pain and toxicity.

b. Penicillinase-producing Neisseria gonorrhoeae (PPNG)

Children should be treated with spectinomycin or cefotaxime in appropriate doses. Ceftriaxone may be useful, but data are unavailable.

c. Special Considerations

Penicillins and cephalosporin regimens that are not recommended are listed on page 26. All patients should have followup cultures, and the source of infection should be identified, examined, and treated. Child abuse should be carefully considered and evaluated.

d. Allergy to Penicillins

Children who are allergic to penicillins or cephalosporins should be treated with spectinomycin, 40 mg/kg IM. Children older than 8 years may be treated with tetracycline, 40 mg/kg/day by mouth, in 4 divided doses, for 5 days. Treatment of complicated disease must be individualized.

GRANULOMA INGUINALE

A. Diagnosis

1. Definitive diagnosis is made when the causative organism, *Calymmatobacterium granulomatis*, is demonstrated by direct smear - "Crush" preparations of air dried scrapings or a biopsied granulation tissue are stained with Wright's or Giemsa stain to reveal the pathognomonic Donovan bodies. More than one preparation may be necessary. The sensitivity of the test correlates with the diligence used in performing it.

2. The typical clinical presentation of single or multiple subcutaneous nodules at the site of inoculation which erode to form painless, beefy, granulomatous ulcers is sufficiently characteristic to establish a presumptive diagnosis among patients epidemiologically linked to definitive cases.

3. The typical clinical presentation (see -2, above) is sufficient to suggest the diagnosis.

B. Treatment

The following regimens are listed in the order of their preference. The minimum duration of treatment is 21 days. However, treatment should be continued until all lesions have completely healed.

1. Tetracycline, 0.5 g by mouth, QID; OR
2. Streptomycin, 0.5 g IM, BID; OR
3. Chloramphenicol, 0.5 g by mouth, TID; OR
4. Gentamicin, 40 mg IM, BID.

NOTE: Erythromycin and sulfamethoxazole/trimethoprim regimens have also been reported to be effective. Penicillins are not effective.

C. Followup

Followup schedules are individualized, but should be at no longer than weekly intervals until the lesion(s) are clearly resolving. Followup should continue until complete resolution has occurred. Patients should understand the importance of abstaining from sex while any lesion is present.

D. Evaluation of Sex Partners

Current sex partners should receive a routine STD evaluation. A particular effort should be made to identify initial subcutaneous nodules, because early treatment decreases the likelihood of serious sequelae. All steady sex partners of cases should be treated prophylactically.

HEPATITIS B

A. Diagnosis

There is evidence to suggest that hepatitis B, hepatitis A, and non-A/non-B hepatitis all are sexually transmitted.

1. The definitive diagnosis of hepatitis B requires that hepatitis B surface antigen (HBsAg) be detected from the serum of a patient in the acute phase of illness.

2. A suggestive diagnosis is made when a patient with the classic clinical syndrome has an epidemiologic link with another definitive, presumptive, or suggestive case within the incubation period (45-180 days).

NOTE: Carriers of HBsAg with concomitant infections with hepatitis A virus or non A/non B virus(es) are a diagnostic challenge. Hepatitis A can be excluded with IgM antibody testing. There is no test to date for non-A/non-B hepatitis.

B. Treatment

Treatment is nonspecific, symptomatic, and supportive. It generally includes rest and adequate diet. Severe cases require hospitalization and, possibly, intravenous therapy to assure fluid and electrolyte balance. All cases of suspected hepatitis should be referred for medical consultation.

C. Followup

All cases should have the HBsAg test repeated 6 months after diagnosis. Those who are positive probably are carriers and should be retested at 1 year. Those positive at one year are definitely carriers and should be referred for consultation and evaluated for chronic hepatitis.

D. Evaluation of Sex Partners

1. Sex partners of individuals with acute hepatitis B or antigen positive individuals are at increased risk of developing hepatitis B.

2. Vaccination should be recommended to individuals at increased risk for hepatitis B infection..

3. Condoms will presumably offer some protection from transmission, but this has not been evaluated.

HUMAN PAPILLOMA VIRUS INFECTION (Condylomata Acuminata, Genital Warts)

A. Diagnosis

The human papilloma virus which causes genital warts cannot be cultivated *in vitro.*

1. A definitive diagnosis, which requires tissue biopsy and histological examination, is usually unnecessary. However, if lesions are very atypical and neoplasia is a consideration, definitive diagnosis is required.

2. A presumptive diagnosis is made on the basis of the typical clinical presentation. Exclude the diagnosis of condylomata lata by obtaining a serologic test for syphilis.

B. Treatment

The treatment of ano-genital warts has not been well studied. No treatment is completely satisfactory. Ano-genital warts have recently been linked to the development of cancer. For these reasons, atypical or persistent warts should be biopsied. A Pap smear is recommended for all women with ano-genital warts. Women with cervical warts should not be treated until the result of the Pap smear is available to guide therapy. While podophyllin is widely used in the treatment of ano-genital warts, some consultants felt that cryotherapy, when available, may be preferable to podophyllin.

1. External Genital/Perianal

a. Drug Regimen of Choice

Podophyllin, 10-25% in compound tincture of benzoin. Apply carefully to wart (avoid normal tissue). Wash off thoroughly in 1-4 hours. If there is no wart

regression after 4 weekly applications, alternative treatments may be used.

OR

Cryotherapy.

NOTE: Podophyllin should not be used during pregnancy.

b. Alternative Therapies
Electrosurgery
Surgical removal (scissor or curette)

2. Vaginal/Cervical

a. Drug Regimen of Choice
Current therapies include cryotherapy and 5 flurouracil. Podophyllin, 10% in compound tincture of benzoin may be used for *vaginal warts only* if great care is taken to ensure that the treated area is dried before removing the speculum. Because podophyllin is absorbed and toxic, use of large amounts should be avoided.

NOTE: Podophyllin is NOT RECOMMENDED for cervical warts.

b. Alternative Therapies
(Same as Above)

3. Accessible Meatal Warts

a. Drug Regimen of Choice
May be treated with podophyllin 10% in compound tincture of benzoin (see above). Great care should be taken to ensure that the treated area is dried before contact with normal mucosa is allowed. Podophyllin must be thoroughly washed off after 1-4 hours.

b. Alternative Therapies
Cryotherapy

4. Urethral Warts
Intraurethral warts should be suspected in men with recurrent meatal warts. Urethroscopy is necessary to diagnose this condition. Intraurethral 5% 5-fluorouracil or Thiotepa may be effective in this condition but have not been adequately evaluated. Podophyllin should not be used.

5. Accessible Anorectal Warts

a. Drug Regimen of Choice
Anorectal warts accessible by anoscope may be treated with cryotherapy or podophyllin 10% in compound tincture of benzoin (see above). Many consultants avoid the use of podophyllin for anorectal warts. However, extreme care must be taken to avoid exposure of normal mucosa to podophyllin. Allow the treated area to dry before removal of the anoscope.

b. Alternative Therapies
Electrocautery

NOTE: Extensive or proximal anorectal warts should be referred for proctological evaluation.

6. Oral Warts
Oral warts should be treated with:
Cryotherapy (e.g., liquid nitrogen, solid carbon dioxide)
Electrosurgery
Surgical removal (scissor or curette)

NOTE: Podophyllin is contraindicated for oral warts.

C. Followup
Patients should return at 1-2 week intervals for retreatment until lesions have disappeared and the skin has healed. Patients should abstain from sexual contact or use condoms to prevent disease transmission until therapy is complete.

D. Evaluation of Sex Partners
Current sex partner should have a routine STD evaluation. Any genital warts which are identified should be treated.

LYMPHOGRANULOMA VENEREUM (LGV)

A. Diagnosis

1. Definitive diagnosis is based on the isolation of the causative organism, *Chlamydia trachomatis*, serotype L. The agent must be aspirated from an infected lymph node and grown in a cell or tissue culture. Cell culturing techniques using McCoy cells are becoming more widely available.

2. The LGV complement fixation test (LGV-CFT) is not sensitive or specific. Other chlamydial infections may be associated with a very high CFT. However, a 4-fold rise in titer in a patient with a typical clinical syndrome constitutes a presumptive diagnosis. Positive microimmunofluorescence or counterimmuno-electrophoresis tests can also yield presumptive diagnoses, but these tests are not generally available.

3. The diagnosis is suggested by the typical clinical presentation and an elevated LGV-CFT.

B. Treatment

1. Drug Regimen of Choice
Tetracycline HCl, 500 mg by mouth, 4 times a day, for at least 2 weeks.

2. Alternative Regimens
The following drugs are active against LGV serotypes *in vitro* but have not been evaluated extensively in culture confirmed cases.
Doxycycline, 100 mg by mouth, twice a day, for at least 2 weeks; OR
Erythromycin, 500 mg by mouth, 4 times a day, for at least 2 weeks; OR
Sulfamethoxazole, 1.0 g by mouth, twice a day, for at least 2 weeks.

NOTE: Other sulfonamides can be used in equivalent dosage.

C. Lesion Management

Fluctuant lymph nodes should be aspirated as needed through healthy adjacent normal skin to prevent spontaneous rupture and drainage. Incision and drainage or excision of nodes will delay healing and should be avoided.

Late sequelae such as stricture and/or fistulae may require surgical intervention.

D. Followup

Clinical response is the best gauge of therapy. Patients should be followed at 1-2 week intervals until all lesions have resolved. For some patients, this has required 9 weeks of antibiotic therapy.

E. Evaluation of Sex Partners

1. Sex partners of patients should be evaluated for other sexually transmitted infections and treated for LGV.
2. There are no proven methods of prevention of LGV. However, using condoms may prevent genital to genital, or genital to rectal transmission.

MOLLUSCUM CONTAGIOSUM

A. Diagnosis

The human poxvirus which causes molluscum contagiosum cannot be cultivated *in vitro.*

1. A definitive diagnosis is made if virus filled vacuoles, the molluscum inclusion bodies, are identified on microscopic examination of specially stained lesion material.
2. Most often, the disease is diagnosed presumptively on the basis of the typical clinical presentation. The single or multiple skin lesions are smooth, firm, shiny, hemispheric papules with umbilicated centers. They are usually found on the trunk and anogenital region.

B. Treatment

Lesions may resolve spontaneously without scarring. However, surgical or medical removal is usually warranted. Procedures directed at individual lesions include:

1. Curettage after local cryoanesthesia; OR
2. Application of cytotoxic substances (podophyllin or silver nitrate); OR
3. Cryotherapy with liquid nitrogen.

C. Followup

Patients should return at 1-2 week intervals until lesions have disappeared and the skin has healed.

D. Evaluation of Sex Partners

Current sex partner should have a routine STD evaluation. Any lesions of molluscum contagiosum found should be treated.

MUCOPURULENT CERVICITIS IN WOMEN

A. Mucopurulent Cervicitis

The presence of mucopurulent endocervical exudate often reflects cervicitis due to chlamydial or gonococcal infection. Nongonococcal mucopurulent cervicitis responds to tetracycline therapy.

1. Treatment

a. If *N. gonorrhoeae* is found on gram stain or culture of endocervical or urethral discharge, treatment should be given as recommended for uncomplicated gonorrhea in adults.

b. If chlamydial infection is proven or suspected, treatment should be given as recommended for chlamydial infection in adults.

2. Alternative Regimens

See alternative regimens for Chlamydia trachomatis infections on p. 20-21.

3. Followup

Posttreatment cultures are indicated for pathogen other than *C. trachomatis* (e.g., *N. gonorrhoeae*) isolated before therapy.

4. Evaluation of Sex Partners

Men exposed to women with mucopurulent cervicitis attributed to gonococcal or chlamydial infection should be evaluated for STD and treated as recommended for sex partners exposed to gonorrhea or chlamydial infection.

NONGONOCOCCAL URETHRITIS (NGU)

Nongonococcal urethritis is a common STD in men. Steady female sex partners are at increased risk for mucopurulent cervicitis which is difficult to diagnose with certainty. *C. trachomatis* is the most frequent cause of nongonococcal urethritis. *Ureaplasma urealyticum* is second; other bacteria and viruses may be less frequent causes of NGU.

A. Diagnosis

1. Definitive diagnosis requires both a and b.
   a. Evidence of urethral inflammation such as discharge on examination or 4 or more poly-morphonuclear (PMN) leukocytes per oil immersion field on microscopic examination of a urethral smear.
   b. Exclusion of gonococcal infection by the appropriate test in men with urethritis.
2. Suggestive diagnosis includes a history of urethral discharge and/or dysuria with negative cultures for gonorrhea; or epidemiologic evidence of recent urethral exposure to an agent known to cause NGU.

B. Treatment

1. Drug Regimen

Tetracycline HCl, 500 mg by mouth, 4 times a day, for at least 7 days;

OR

Doxycycline, 100 mg by mouth, twice a day, for at least 7 days.

2. **Alternative Regimen** (for patients in whom tetracyclines are contraindicated or not tolerated)

Erythromycin base or stearate, 500 mg by mouth, 4 times daily, for 7 days.

OR

Erythromycin ethylsuccinate 800 mg by mouth 4 times daily for 7 days.

C. Followup

Patients should be advised to return if symptoms persist or recur.

D. Evaluation of Sex Partners

All persons who are sex partners of patients with NGU should be examined for STD and promptly treated with one of the above regimens.

E. Persistent or Recurrent NGU

Recurrent NGU may be due to failure to treat the sex partners. Patients with persistent or recurrent objective signs of urethritis after adequate treatment of the patient and partners warrant further evaluation for less common causes of urethritis.

PEDICULOSIS (CRABS)

A. Diagnosis

1. Definitive diagnosis is made by finding lice or nits attached to genital hairs.
2. Presumptive diagnosis is made when a patient with a history of recent exposure to pubic lice has pruritic erythematous macules, or papules on secondary excoriations in the genital region.
3. A suggestive diagnosis is made when the patient reports the finding of "crab" lice in the genital region. It is also suggestive when the patient has been recently exposed to a definitive or presumptive case.

B. Treatment

Lindane (1%) lotion or cream applied in a thin layer to the infested and adjacent hairy areas and thoroughly washed off after 8 hours; OR Lindane (1%) shampoo applied for 4 minutes and then thoroughly washed off; OR Pyrethrins and piperonyl butoxide (non-prescription) applied to the infested and adjacent hairy area and washed off after 10 minutes.

NOTE: **Lindane is not recommended for pregnant or lactating women, small children, or in patients with severe excoriations because it may be absorbed percutaneously.**

Retreatment is indicated after 7 days if lice are found, or eggs are observed at the hair-skin junction. Clothing or bed linen which may have been contaminated by the patient within the past 2 days, should be washed and/or dried by machine (hot cycle in each) or dry cleaned.

C. Followup

Patients should be reexamined in 1 week. Since ova may survive, a second treatment may be necessary. Sexual or close physical contact should be avoided until after treatment. Patients should return if the problem is not cured or recurs.

D. Evaluation of Sex Partners

All sex partners should receive a routine STD evaluation and treated as recommended for pediculosis.

E. Special Considerations

Pediculosis of the eyelashes should be treated by the application of occlusive ophthalmic ointment to the eyelid margins twice daily for 10 days to smother lice and nits. Lindane or other drugs should not be applied to the eyes.

Pruritis may persist after adequate treatment because of an allergic reaction and/or irritation. Discussing posttreatment pruritis with patients may prevent unnecessary retreatment.

PELVIC INFLAMMATORY DISEASE (PID): Endometritis, Salpingitis, Parametritis, and/or Peritonitis

Pelvic inflammatory disease is defined as the clinical syndrome resulting from the ascending spread of microorganisms from the vagina and endocervix to the endometrium, the fallopian tubes and/or to contiguous structures. Most likely PID is caused by more than one organism.

PID is a common and important complication of lower genital tract infection in women in this country. *N. gonorrhoeae* and *C. trachomatis* frequently are associated with PID. Other organisms, such as anerobes and facultative gram- negative rods also have been associated with PID. It is not possible to clinically distinguish disease caused by various organisms independently. Tables 5 through 8 list clinical and laboratory findings which should prompt the clinician to consider the diagnosis of PID.

TABLE 5. Factors Predisposing to PID:

Multiple sex partners.
History of previous PID.
Menstruation.
IUD.

TABLE 6. Signs and Symptoms Suggesting PID:

Low abdominal pain.
Low abdominal tenderness.
Adnexal tenderness.
Tenderness on cervical motion.

TABLE 7. Signs and Symptoms Associated With PID:
Tender adnexal mass(es).
Purulent endocervical discharge.
Fever and chills.
Nausea and vomiting.
Anorexia.
Adynamic ileus.

TABLE 8. Laboratory Findings Supportive of the Diagnosis of PID:
Positive culture for *N. gonorrhoeae* or *C. trachomatis* from the cul-de-sac or endocervix.
Positive gram stain for intracellular gonococci from the cul-de-sac or endocervix.
Elevated white blood cell count.
Elevated erythrocyte sedimentation rate.

A. Diagnosis

1. Definitive diagnosis of PID consists of direct visualization of inflammed (edema, hyperemia, or tubal exudate) fallopian tube(s) on laparoscopy, laparotomy, or biopsy evidence of salpingitis. Only a confirmed culture of a biopsy of the fallopian tube positively identifies the etiology of salpingitis.

2. A presumptive diagnosis of PID can be made on clinical grounds alone (see Tables 5-8). In those patients where the differential diagnosis includes other serious conditions such as acute appendicitis or ectopic pregnancy, referral for consultation, hospitalization, and/or laparoscopy is warranted.

B. Treatment

Etiologic agents of PID include *N. gonorrhoeae*, *C. trachomatis*, anaerobic bacteria (which include Bacteroides and gram positive cocci), facultative gram negative rods (such as *Escherichia coli*), and *Mycoplasma hominis*; *Actinomyces israelii* has been found in patients with long standing IUDs. In the individual patient it is often impossible to differentiate among these organisms. Current thought suggests that the etiology may be due to more than a single organism. Treatment regimens should be used which are active against the broadest range of these organisms.

1. Hospitalization and Inpatient Therapy

Hospitalization of patients with acute PID should be strongly considered when: (1) the diagnosis is uncertain; (2) surgical emergencies such as appendicitis and ectopic pregnancy must be excluded; (3) a pelvic abscess is suspected; (4) severe illness precludes outpatient management; (5) the patient is pregnant; (6) the patient is unable to follow or tolerate an outpatient regimen; (7) the patient has failed to respond to outpatient therapy; or (8) the clinical followup after 48-72 hours of starting antibiotic treatment cannot be arranged. Many experts recommend that all patients with PID be hospitalized for treatment.

a. Rationale for Selection of Antimicrobials

The treatment of choice is not established. No single agent is active against the entire spectrum of pathogens. Several antimicrobial combinations do provide a broad spectrum of activity against the major pathogens *in vitro*, but none have been adequately evaluated for clinical efficacy in PID.

b. Examples of Combination Regimens with Broad Activity Against Major Pathogens in PID:

Doxycycline, 100 mg IV, twice daily,

PLUS

Cefoxitin, 2.0 g IV, 4 times daily.

Continue drugs IV for at least 4 days and at least 48 hours after patient defervesces. Continue doxycycline 100, mg by mouth, twice a day after discharge from the hospital to complete 10-14 days of therapy.

OR

Clindamycin, 600 mg IV, 4 times a day,

PLUS

Gentamicin, 2.0 mg/kg IV, followed by 1.5 mg/kg, 3 times a day, in patients with normal renal function.

Continue drugs IV for at least 4 days and at least 48 hours after patient defervesces. Continue clindamycin, 450 mg by mouth, 4 times a day, after discharge from the hospital to complete 10-14 days of therapy.

2. Ambulatory Therapy

When the patient is not hospitalized, the following regimen is recommended:

Cefoxitin, 2.0 g IM; OR amoxicillin, 3.0 g by mouth; OR ampicillin, 3.5 g by mouth; OR aqueous procaine penicillin G, 4.8 million units IM, divided at 2 injection sites; OR ceftriaxone 250 mg IM. Each of these regimens except ceftriaxone is accompanied by probenecid, 1.0 g by mouth,

FOLLOWED BY

Doxycycline, 100 mg by mouth, twice a day, for 10-14 days.

NOTE: Tetracycline HCl can also be used in a dose of 500 mg by mouth, 4 times a day, but is less active against certain anaerobes, and requires more frequent dosing; both represent drawbacks in treatment of PID.

Cefoxitin or an equivalently effective cephalosporin plus doxycycline (or tetracycline) provides activity against *N. gonorrhoeae*, penicillin resistant isolates, and *C. trachomatis*. PPNG associated PID is not adequately treated with amoxicillin, ampicillin or aqueous procaine penicillin in combination with doxycycline.

C. Followup

PID treated in an outpatient clinic requires close medical followup. The diagnostic criteria are less precise than with other STDs. Therapeutic regimens have higher failure rates. Successful treatment depends heavily on the patient's compliance with relatively long-term therapy. Surgical interven-

tion may be needed in some cases.
Followup includes:

1. Evaluation, with bimanual examination, of patients 2-3 days after the start of therapy for symptomatic improvement, drug reactions, and compliance.
2. Repeat bimanual examination and endocervical and rectal cultures 4-7days after completing therapy.
3. Confirmation of clinical resolution by repeating examination and endocervical culture 4-6 weeks after completing therapy.

D. Evaluation of Sex Partners

1. All sex partners exposed to gonococcal PID within the 60 days prior to the patient's initial clinical assessment should come to the clinic for routine patient evaluation (see Medical Care Section II.C.1, 2, 3, 4). Each exposure site should be cultured or gram stained as appropriate.
2. All persons who are sex partners of patients with PID should be examined for STD and promptly treated with a regimen effective against uncomplicated gonococcal **and** chlamydial infection.

E. Intrauterine Device (IUD)

The intrauterine device increases the risk of the development of pelvic inflammatory disease. Although the exact effect of removing an IUD on the response of acute salpingitis to antimicrobial therapy and on the risk of recurrent salpingitis is unknown, removal of the IUD is recommended soon after antimicrobial therapy has been initiated. When an IUD is removed, contraceptive counseling is necessary. (See Appendix G.)

SCABIES

A. Diagnosis

1. Definitive diagnosis requires that the mite, its eggs, larvae, or feces be identified grossly or microscopically. Specimens are obtained by scraping papules or burrows. Common sites of infection include the wrists, webbing between fingers, the flexor surface of the wrist, anterior axillary folds, the penis and the inner aspects of the upper thigh.
2. Presumptive diagnosis is made when a patient with a history of recent exposure to scabies demonstrates the primary lesion, which is the burrow, or has characteristic pruritic, erythematous, papular eruptions. Excoriations and secondary infections are common. The pruritis is usually worse at night.
3. The diagnosis is suggested by the typical clinical presentation.

B. Treatment

1. Adults and Older Children

a. Drug Regimen of Choice

Lindane (1%), 1 oz. of lotion, or 30 g of cream applied thinly to all areas of the body from the neck down and washed off thoroughly after 8 hours.

NOTE: Not recommended for pregnant or lactating women, small children, or in patients with severe excoriations because it may be absorbed percutaneously.

b. Alternative Therapies:

Crotamiton (10%) applied to the entire body from the neck down, nightly, for two nights and washed off thoroughly 24 hours after the second application; OR
Sulfur (6%) in petrolatum, applied to the entire body from the neck down, nightly for three nights. Patients may bathe before reapplying the drug and should bathe 24 hours after the final application.

2. Infants, Young Children (10 Years Old), Pregnant and Lactating Women

Crotamiton (10%) as noted above; OR
Sulfur (6%) in petrolatum, as noted above.

C. Followup

Patients should be examined in 1 week. Since ova may survive, a second treatment may be necessary. Sexual or close physical contact should be avoided until after treatment. Patients should return if the problem is not cured or recurs.

D. Evaluation of Sex Partners

All sex partners should receive a routine STD evaluation. Recent sex partners and close household contacts should be treated as recommended for scabies.

E. Special Considerations

Pruritus may persist for several weeks after adequate therapy. A single retreatment after one week may be appropriate if there is no clinical improvement. Additional weekly treatments are warranted only if live mites can be demonstrated.

Clothing or bed linen which may have been contaminated by the patient within the past 2 days, should be washed and/or dried by machine (hot cycle in each) or dry cleaned.

SYPHILIS

A. Diagnosis

- **Criteria for primary syphilis.**

1. The diagnosis of primary syphilis is definite if *Treponema pallidum* is demonstrated by darkfield microscopy or by Direct Fluorescent Antibody Stain for *T. pallidum* (DFATP) in material from a chancre or aspirate from a regional lymph node. NOTE: Commensal spirochetes found in the oropharynx may be mistaken for *T. pallidum* in darkfield microscopy when examining material from the oral cavity; therefore, such spirochetes should be confirmed by DFATP.
2. A presumptive diagnosis of primary syphilis is made when patients have one or more typical lesions (chancres)

and:

a. Reactive nontreponemal tests but no previous history of syphilis or reactive nontreponemal tests.
b. The titer of the present nontreponemal in test is ≤ 4-fold than the last test.
c. They have appeared within 10-90 days of exposure to a partner with definitive or presumptive diagnosis of primary, secondary, or early latent syphilis.

3. The diagnosis of primary syphilis is suggested by a lesion resembling a chancre at a site of sexual exposure and a characteristic clinical course, regardless of the result of the nontreponemal test.

NOTE: Many patients with genital lesions apply topical substances to their lesions prior to seeking professional evaluation. These preparations may produce a negative darkfield examination even though the patient has primary syphilis. In such cases, the darkfield examination should be repeated one and two days after discontinuing all such preparations in an effort to establish a definitive diagnosis.

- **Criteria for secondary syphilis.**

1. A definitive diagnosis of secondary syphilis can be made only in patients with positive nontreponemal serologic tests. Darkfield microscopic (or FA) demonstration of *T. pallidum* in material from skin lesions or lymph nodes confirms the diagnosis.

2. A presumptive diagnosis of secondary syphilis applies to patients with signs of secondary syphilis (see Table 1) and either a newly reactive serologic test or a ≤ 4-fold increase in titer over the last known nontreponemal test.

TABLE 1. **Typical Signs of Secondary Syphilis: (One or more may be present)**

Bilaterally symmetrical macular, papular, follicular, papulosquamous, or pustular skin lesions.
Alopecia (without scar formation).
Loss of the eyelashes and lateral third of the eyebrows.
Iritis.
Condylomata lata (moist papules, usually in anogenital region or mouth).
Mucous patches of the oropharynx or cervix.
Generalized lymphadenopathy.
Fever and malaise.
Splenomegaly.

3. A small percentage of patients with secondary syphilis may have a nonreactive nontreponemal test because of a prozone phenomenon. A prozone reaction occurs in nontreponemal tests when an excess amount of anticardiolipin (reaginic) antibody interferes with the test result. This inhibitory effect of excess antibodies can be overcome by diluting the serum and repeating the nontreponemal test.

- **Criteria for latent syphilis.**

1. Since definitive diagnoses require positive identification of *T. pallidum*, a definitive diagnosis of latent syphilis *cannot be made under usual circumstances.*

2. Presumptive diagnosis of early latent syphilis is made when an asymptomatic patient with nontreponemal and treponemal tests is known to have had within the previous year: a nonreactive serological test; or symptoms highly suggestive of primary or secondary syphilis; or exposure to a sex partner with definitive or presumptive primary, secondary, or early latent syphilis; or a ≤ 4-fold increase in titer on serial nontreponemal tests.

3. Presumptive diagnosis of late latent syphilis is made when an asymptomatic patient with newly discovered reactive nontreponemal and treponemal tests does not meet the other criteria for early latent syphilis.

- **Criteria for patients previously treated for syphilis.**

To establish a new diagnosis of syphilis in patients previously treated, either the darkfield (or FA) exam must be positive (definitive diagnosis), or there must be a 4-fold increase in a quantitative nontreponemal titer (presumptive diagnosis).

- **Criteria for late acquired syphilis.**

Untreated late syphilis may be manifested by a broad range of signs and symptoms, varying from the inapparent to those indicating severe damage to one or more organ systems. However, late syphilis is rarely communicable. Patients with reactive nontreponemal and treponemal tests and indications of neurosyphilis, cardiovascular or other forms of late syphilis should be referred for appropriate medical evaluation and management.

- **Criteria for early congenital syphilis.**

1. Early congenital syphilis is diagnosed definitively when *T. pallidum* is demonstrated by darkfield (or FA) examination of material from nasal discharges or skin lesions of a neonate.

2. A presumptive diagnosis applies to any infant in whom a ≤ 4-fold increase in titer over the infant's previous titer is demonstrated. A presumptive diagnosis is made in symptomatic neonates with reactive nontreponemal tests if their mothers were not adequately treated for syphilis.

NOTE: If the neonate is asymptomatic, has a positive serology, and the mother was not adequately treated for her infection with penicillin, the baby should be treated without awaiting criteria for a presumptive diagnosis.

B. Treatment

1. Early syphilis (primary, secondary, latent syphilis of less than one year's duration)
Benzathine penicillin G, 2.4 million units IM, at a single session.

Patients who are allergic to penicillin:
Tetracycline HCl, 500 mg by mouth, four times a day, for 15 days.

Tetracycline appears to be effective, but has been evaluated less extensively than penicillin. Patient compliance with this regimen may be difficult so care should be taken to encourage optimal compliance.

Penicillin-allergic patients who cannot tolerate tetracycline, should have their allergy confirmed. For these patients there are two options:

A. If compliance and serologic followup can be assured, administer erythromycin, 500 mg by mouth, 4 times a day, for 15 days.

B. If compliance and serologic followup cannot be assured, the patient should be referred for medical consultation and possible penicillin desensitization.

2. Syphilis of more than one year's duration, except neurosyphilis (latent syphilis of indeterminate or more than one year's duration, cardiovascular, or late benign syphilis):

   Benzathine penicillin G, 7.2 million units total, 2.4 million units IM weekly, for three successive weeks.

   The optimal treatment schedules for syphilis of greater than one year's duration have been less well established than schedules for early syphilis. In general, syphilis of longer duration requires more prolonged therapy.

   Therapy is recommended for established cardiovascular syphilis; antibiotics may not reverse the pathology associated with this disease.

   There are no published clinical data which adequately document the efficacy of drugs other than penicillin for syphilis of more than one year's duration. Cerebrospinal fluid examination, which usually requires hospitalization, should be performed before therapy with these regimens.

   Patients who are allergic to penicillin:
   Tetracycline HCl, 500 mg by mouth, 4 times a day, for 30 days. Patient complicance with this regimen may be difficult so care should be taken to encourage optimal compliance.

   Penicillin-allergic patients who cannot tolerate tetracycline, should have their allergy confirmed. For these patients there are two options:

   A. If compliance and serologic followup can be assured, administer erythromycin, 500 mg by mouth, 4 times a day, for 30 days.

   B. If compliance and serologic followup cannot be assured, the patient should be referred for medical consultation and possible penicillin desensitization.

NOTE: Cerebrospinal fluid (CSF) examination should be performed in patients with clinical symptoms or signs consistent with neurosyphilis. This examination is also desirable in other patients with syphilis of greater than one year's duration to exclude asymptomatic neurosyphilis.

3. Neurosyphilis
   Published studies show that a total dose of 6.0-9.0 million units of penicillin G over a 3-4 week period results in a satisfactory clinical response in approximately 90 percent of patients with neurosyphilis. This information must be considered along with the observation that regimens employing benzathine penicillin or procaine penicillin in doses under 2.4 million units daily do not consistently provide treponemicidal levels of penicillin in CSF, and with several case reports of the failure of such regimens to cure neurosyphilis. Patients with suspected neurosyphilis merit evaluation within a hospital.

   Potentially effective regimens, none of which have been adequately studied include:

   Aqueous crystalline penicillin G, 12-24 million units IV/day (2-4 million units every 4 hours) for 10 days, followed by benzathine penicillin G, 2.4 million units IM, weekly for 3 doses;

   OR

   Aqueous procaine penicillin G, 2.4 million units IM, daily, plus probenecid 500 mg by mouth, 4 times a day, both for 10 days, followed by benzathine penicillin G, 2.4 million units IM, weekly for 3 doses;

   OR

   Benzathine penicillin G, 2.4 million units IM, weekly for 3 doses.

   Patients with histories of allergy to penicillin should have their allergy confirmed.

4. Syphilis in Pregnancy
   All pregnant women should have a nontreponemal serologic test for syphilis, such as the VDRL or RPR test, at the time of the first prenatal visit. The treponemal tests such as the FTA-ABS test should not be used for routine screening. In women suspected of being at high risk for syphilis, a second nontreponemal test should be performed during the third trimester prior to delivery. Finally, at delivery the cord blood should be tested for syphilis antibody.

   Seroreactive patients should be expeditiously evaluated. This evaluation should include a history and physical examination, as well as a quantitative nontreponemal test and a confirmatory treponemal test.

   If the FTA-ABS test is nonreactive and there is no clinical evidence of syphilis, treatment may be withheld. Both the quantitative nontreponemal test and the confirmatory test should be repeated within 4 weeks. If there is clinical or serologic evidence of syphilis or if the diagnosis of syphilis cannot be excluded with reasonable certainty, the patient should be treated as outlined below.

Patients for whom there is documentation of adequate treatment for syphilis in the past need not be retreated unless there is clinical or serologic evidence of reinfection such as darkfield-positive lesions or a 4-fold titer rise of a quantitative nontreponemal test.

For patients at all stages of pregnancy who are not allergic to penicillin: Penicillin in dosage schedules appropriate for the stage of syphilis as recommended for the treatment of nonpregnant patients.

Patients of all stages of pregnancy who have documented allergy to penicillin:

A. If compliance and serologic followup cannot be assured, the patient should be hospitalized and managed in consultation with a medical specialist.
B. If compliance and serologic followup can be assured, administer erythromycin in dosage schedules appropriate for the stage of syphilis as recommended for the treatment of nonpregnant patients. Infants born to mothers treated during pregnancy with erythromycin for early syphilis should be treated with penicillin.

Tetracycline is not recommended in pregnant women because of potential adverse effects on the fetus.

Pregnant women who have been treated for syphilis should have monthly quantitative nontreponemal serologic tests for the remainder of the current pregnancy. Women who show a 4-fold rise in titer should be retreated. After delivery, followup is as outlined for nonpregnant patients.

5. Congenital syphilis

Congenital syphilis may occur if the mother has syphilis during pregnancy. If the mother has received adequate penicillin treatment during pregnancy, the risk to the infant is minimal. However, all infants should be examined carefully at birth and at frequent intervals thereafter until nontreponemal serologic tests are negative.

Infected infants are frequently asymptomatic at birth and may be seronegative if the maternal infection occurred late in gestation. Infants should be treated at birth if maternal treatment was inadequate, unknown, with drugs other than penicillin, or if adequate follow up of the infant cannot be ensured.

Infants with congenital syphilis should have a CSF examination before treatment.

a. Symptomatic Infants or Asymptomatic Infants with Abnormal Cerebrospinal Fluid

Aqueous crystalline penicillin G, 50,000 units/kg IM or IV, daily, in two divided doses for a minimum of 10 days;

OR

Aqueous procaine penicillin G, 50,000 units/kg IM, daily, for a minimum of 10 days.

b. Asymptomatic Infants with Normal Cerebrospinal Fluid

Benzathine penicillin G, 50,000 units/kg IM, in a single dose.

Although benzathine penicillin has been previously recommended and widely used, published clinical data on its efficacy in congenital neurosyphilis are lacking. If neurosyphilis cannot be excluded, the aqueous or procaine penicillin regimens are recommended. Only penicillin regimens are recommended for neonatal congenital syphilis.

Penicillin therapy for congenital syphilis after the neonatal period should be with the same dosages used for neonatal congenital syphilis. For larger children, the total dose of penicillin need not exceed the dosage used in adult syphilis of more than one year's duration. After the neonatal period, the dosage of tetracycline for congenital syphilis in patients who are allergic to penicillin should be individualized but need not exceed dosages used in adult syphilis of more than one year's duration. Tetracycline should not be given to children less than 8 years of age.

C. Followup

All patients with early syphilis and congenital syphilis should be encouraged to return for repeat quantitative nontreponemal tests at least 3, 6, and 12 months after treatment. In these patients, quantitative nontreponemal test titers will decline to nonreactive or low titer reactive within a year following successful treatment with benzathine penicillin G. Serologic test results decline more slowly in patients treated for disease of longer duration. Patients with syphilis of more than one year's duration should also have a repeat serologic test 24 months after treatment. Careful followup serologic testing is particularly important in patients treated with antibiotics other than penicillin. Examination of CSF should be planned as part of the last followup visit after treatment with antibiotics other than penicillin in the recommended dosages.

All patients with neurosyphilis must be carefully followed with periodic serologic testing, clinical evaluation with repeat CSF examination at 6 month intervals until the CSF findings return to normal.

The possibility of reinfection should always be considered when retreating patients with early syphilis. A CSF examination should be performed before retreatment unless reinfection and a diagnosis of early syphilis can be established.

Retreatment should be considered when:

1. Clinical signs or symptoms of syphilis persist or recur;
2. There is a 4-fold increase in the titer of a nontreponemal test;
3. An initially high-titer nontreponemal test fails to decrease 4-fold within a year.

Patients should be retreated with the schedules recommended for syphilis of more than one year's duration. In general, only one retreatment course is indicated because patients may maintain stable, low titers of nontreponemal tests or have irreversible anatomical damage.

D. Evaluation of Sex Partners

1. Effective followup of sex partners requires that anyone with syphilis or at risk of acquiring it, be identified and evaluated promptly. Table 2 lists the most productive time frames to find untreated, incubating, or infected sex partners of patients with syphilis.

TABLE 2. The Intervals of Greatest Likelihood for Finding Untreated, Incubating, or Infected Sex Partners of Syphilis Patients.

Patient's Stage of Syphilis	Examine All Sex Partners Exposed to the Patient:
Primary	While he or she is symptomatic and during the 3 months prior to the onset of symptoms.
Secondary	While he or she is symptomatic and during the 6 months prior to the onset of symptoms.
Early Latent	During the 12 months prior to making the diagnosis.
Late	Who are steady (e.g., marital) sex partners, or children of infected women.

2. All sex partners should come to the clinic for routine evaluation (see Medical Care Section, C.1, 2, 3, 4), which includes a serologic test for syphilis.

3. Sex partners should receive treatment appropriate for the results of their evaluations. Even when such evaluations do not yield a presumptive or definitive diagnosis, those exposed to early syphilis within the preceding 3 months and others who, on epidemiologic grounds, are at high risk for syphilis should be treated as for early syphilis. Nevertheless, clinicians should make every effort to establish diagnoses in these cases.

VULVOVAGINITIS

Some pathogenic organisms known to cause vulvovaginitis may be sexually transmitted. Although serious medical complications have not been described, these infections occur frequently and are a source of discomfort for women.

A. Diagnosis

All levels of diagnosis require a history suggestive of vulvar or vaginal inflammation or finding evidence of such inflammation on exam. Excessive or malodorous vaginal discharge, vulvar or vaginal pruritus, or tenderness as well as vaginal lesions are suggestive of vulvovaginitis.

1. Vulvovaginitis is associated with infections due to *Trichomonas vaginalis*, *Candida species*, and *Gardnerella vaginalis*. Definitive diagnosis also requires that *Trichomonas vaginalis*, *Candida species*, or *Gardnerella vaginalis* be identified by culture, or other means of identification in wet mounts from the vagina.

2. There are no presumptive criteria for diagnosing trichomoniasis.

3. Presumptive diagnosis of candida vulvovaginitis requires that budding cells or hyphae be found by:
   a. KOH mount of vaginal discharge; or
   b. Gram stain of vaginal discharge; or
   c. KOH preparation of a scraping taken from inflammed vulvar skin.

4. Presumptive diagnosis of Gardnerella vulvovaginitis requires that:
   a. "Clue cells" be identified in a saline wet mount or gram stain of vaginal discharge; or
   b. A mixture of vaginal discharge and 10% KOH liberates an "amine-like" or "fishy" odor.

5. A suggestive diagnosis of vulvovaginitis is made when evidence of inflammation is present, but a causative agent is not identified.

B. Treatment

1. Trichomoniasis

Metronidazole, 2.0 g by mouth, in a single dose.

As an alternative, metronidazole may be administered as 250 mg by mouth, 3 times a day, for 7 days.

NOTE: Asymptomatic women with trichomoniasis should be treated in the same manner as symptomatic women.

a. Treatment in Pregnancy

Metronidazole is contraindicated in the first trimester of pregnancy and should be avoided throughout pregnancy. Clotrimazole, 100 mg intravaginally at bedtime for 7 days is an alternative and may produce symptomatic improvement as well as cure in some women. Other local treatments (e.g., vinegar douches or acidified gels) may be used for symptomatic relief but have low cure rates. Lactating women may be treated with metronidazole 2.0 g, by mouth, in a single dose, however, breast feeding should be interrupted for at least 24 hours after therapy.

b. Treatment of Neonates

Infants with symptomatic trichomoniasis or with persistent urogenital trichomonal colonization beyond the fourth week of life can be treated with metronidazole, 10-30 mg/kg daily, for 5-8 days.

2. Gardnerella-Associated Vaginalis

Metronidazole, 500 mg by mouth, twice a day, for 7 days.

Ampicillin or amoxicillin 500 mg by mouth, 4 times a day, for 7 days is less effective but may be used for pregnant patients or individuals for whom metronidazole is contraindicated.

Treatment is not recommended for asymptomatic carriers of *Gardnerella vaginalis*.

If Gardnerella vaginalis coexists with candidiasis and/or trichomoniasis, treat the other condition(s) first. Reevaluate after treatment. If signs and symptoms persist then treat for *Gardnerella vaginalis*.

3. **Candidiasis**

Nystatin, 1 vaginal suppository BID, for 2 weeks;

OR

Miconazole nitrate 2% vaginal cream, 1 applicatorful, intravaginally at bedtime, for 7 days (and applied externally for vulvitis);

OR

Clotrimazole, 1 vaginal suppository daily, for 7 days.

C. Followup

Followup schedules are individualized according to clinical response. Tests of cure such as saline wet mounts, KOH preps, and gram stains or vaginal discharge for patients who have clinically responded to therapy are optional. For patients with trichomoniasis, tests of cure should be sought whenever possible. Resistance to metronidazole has been observed, but is rare.

D. Drug Interactions

Some patients taking metronidazole may experience a "disulfiram reaction" after the ingestion of alcohol. Patients should be warned that ingestion of alcohol while on metronidazole may result in tachycardia, palpitations, flushing, and nausea. Also, metronidazole may potentiate the anticoagulate effects of warfarin.

E. Evaluation of Sex Partners

1. All sex partners should be evaluated for STDs.
2. Sex partners of women with trichomoniasis should be evaluated and treated with metronidazole 2.0 gm by mouth in a single dose.
3. Sex partners of women with candidiasis should be examined for balanitis and other sexually transmitted infections.
4. Treatment of male sex partners of women with Gardnerella vaginitis is controversial and may be indicated in specific instances of recurrence in these woman. Available data suggest that either metronidazole, 500 mg by mouth, twice a day, for 7 days or ampicillin, 500 mg by mouth, 4 times a day, for 7 days should be used.

PART III

APPENDICES

APPENDIX A

QUALITY ASSURANCE

A quality assurance (QA) program can be an effective means to help ensure that excellent patient services and care are being provided. The implementation of a QA program is critical to decision-making concerning the quality of care provided, standards and criteria, budget allocations, staffing patterns, or program planning.

A combination of procedures is necessary for a well-rounded, comprehensive quality assurance program as discussed in Part I of this document. Examples of forms used in the very successful quality assurance program of the Dayton, Ohio STD Clinic are provided in this appendix. This begins with a flow chart of the audit cycle and a brief description of its components. Following this are some forms used in the Dayton QA system.

Audit Criteria Form

Establishing an audit criteria is a necessary first step in a QA program. The audit criteria from Dayton is 21 pages long, but only a few selected pages of it are included here for illustration. The audit criteria is merely an expansion of the clinic protocols developed to be precise, descriptive, and measurable in terms that can be used by non-STD to evaluate elements of desired performance by comparing it with medical records.

Data Retrieval and Display Form

Charts are pulled, usually by an objective non-STD program reviewer, and screened for agreement with the norm or standard. The reviewer compares the criteria with the actual documentation in the chart and records any variations on this form.

Audit Summary Form

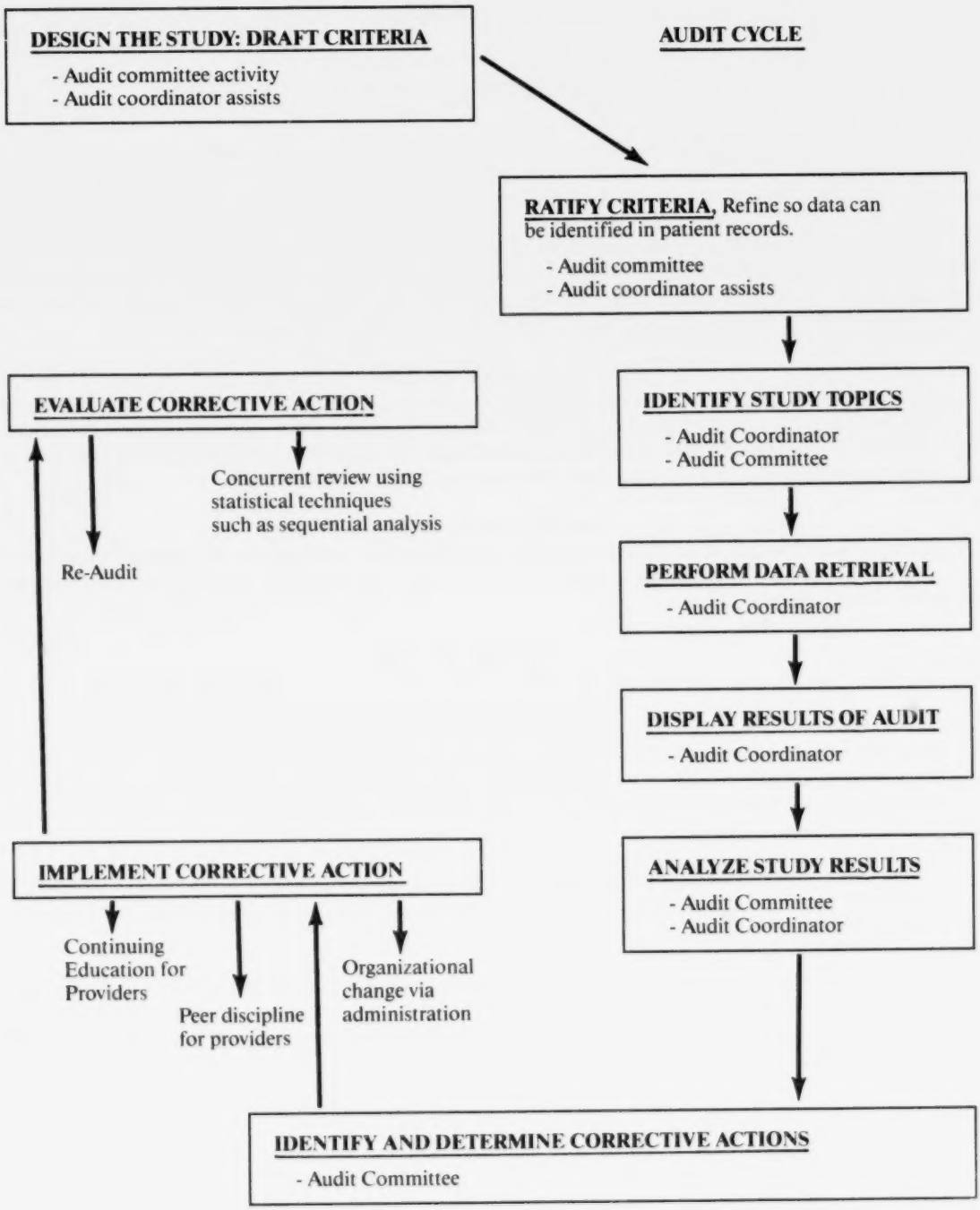
The charts with variations then are summarized and submitted to the audit committee on this form.

Corrective Action Form

The audit committee determines if there was clinical justification for each variation. Unjustified variations are called defenciencies and the records with defenciencies are analyzed to determine the reason the deficiency occured. The committee attempts to determine the type of defenciency that occured and what action needs to be taken and records its findings on this form.

In some cases, variations are deemed legitimate and occurred because the audit criteria (and clinic protocols) failed to anticipate the situation encountered. In such instances, the committee will recommend changes in the criteria and protocols.

While useful in identifying trends in the quality of clinical care, the chart audit does not give a complete picture, nor can it serve as the only method for evaluating the quality of patient services delivered. Multiple methods, including direct observation of performance, are needed to evaluate both the documentation of care and the quality of care delivered.


DESIGN THE STUDY: DRAFT CRITERIA
- Audit committee activity
- Audit coordinator assists
AUDIT CYCLE
RATIFY CRITERIA, Refine so data can be identified in patient records.
- Audit committee
- Audit coordinator assists
IDENTIFY STUDY TOPICS
- Audit Coordinator
- Audit Committee
PERFORM DATA RETRIEVAL
- Audit Coordinator
DISPLAY RESULTS OF AUDIT
- Audit Coordinator
ANALYZE STUDY RESULTS
- Audit Committee
- Audit Coordinator
IDENTIFY AND DETERMINE CORRECTIVE ACTIONS
- Audit Committee
IMPLEMENT CORRECTIVE ACTION
Continuing Education for Providers
Peer discipline for providers
Organizational change via administration
EVALUATE CORRECTIVE ACTION
Concurrent review using statistical techniques such as sequential analysis
Re-Audit

AUDIT CYCLE NARRATIVE

1. DESIGN THE STUDY; DRAFT CRITERIA

Criteria are developed by the audit committee. Valid criteria should permit objective review of the quality of care provided to all patients. Criteria are stated in measurable terms, precise enough to permit accurate evaluation. Criteria may be statements of optimal achievable care, validations of diagnosis or processes of care and patient management. Each criteria consists of three parts: 1. An element which is a statement of an expected goal or procedure; 2. A standard of percentage which is the number of times that the element is expected to be met in percentage. This percent can be either 0%, which is being met none of the time or 100%, when the criteria is expected to be met all of the time; 3. An exception, which is any justifiable non conformance to the element. An exception is not necessary in every criterion.

2. IDENTIFY STUDY TOPICS

An audit committee must first select a topic of study. This may be a condition, a diagnosis, a specific problem, etc. A decision must also be made about the number of records to study per year. The study topic may also include age groups, sex and time frame of records.

3. RATIFY CRITERIA, REFINE SO THAT DATA CAN BE IDENTIFIED IN PATIENT RECORDS

The criteria must be reviewed, ratified and refined. The committee must determine that each criterion is of sufficient importance to warrant review of the medical record if it is not met. The data retriever must be confident with the criteria and know where each element can be found in the record. The committee assures this by adding an explanation to each criterion. This explanation may be the location of information, a definition of a term or procedure, etc.

4. PERFORM DATA RETRIEVAL AND DISPLAY RESULTS

Charts are pulled by the audit coordinator according to the topic and are screened for variations. The criteria are compared to the actual documentation in the record, noting any variations. These variations are displayed while retrieval is done as a first draft. The records with no variations are refiled, but the records with variations are brought to the audit committee meeting for review.

5. DISPLAY RESULTS OF AUDIT FINDINGS

Results are displayed in a second draft for presentation at the audit committee meeting by the audit coordinator. The coordinator uses this draft to then add the results of the committee findings during the meeting.

6. ANALYZE STUDY RESULTS IN LIGHT OF AUDIT RESULTS MEASURED

The audit committee determines if there was clinical justification for each variation. Unjustified variations are termed deficiencies and only these records are further analyzed to find the reason that the deficiency occurred.

7. IDENTIFY AND DETERMINE CORRECTIVE ACTION

The audit committee's goal now is to select the appropriate action to solve the problem. There are basically three types of deficiencies which require specific actions. These deficiencies and actions can be in the areas of knowledge, environment or feedback. Deficiencies in knowledge may require a solution of further education to the providers such as in-service programs, further orientation or demonstration. Deficiencies in environment may require a restructuring to reduce interference, rearrangement of tasks or needed tools. Deficiencies in feedback may require further information to the provider.

8. IMPLEMENT CORRECTIVE ACTION

The committee reports its findings to administration and suggests implementation of corrective action.

9. EVALUATE CORRECTIVE ACTION

The committee's next goal is to see if the action corrected the problem. This can be done by a re-audit of similar records in a time frame after the action was implemented and review of statistical data for sequential analysis. If similar deficiencies are found again, then the committee must re-evaluate the problem and implement changes to their original corrective action.

AUDIT CRITERIA **QUALITY ASSURANCE**

QUANTITATIVE _____ QUALITATIVE X

COMMITTEE: SEXUALLY TRANSMITTED DISEASE DATE: 2-1-85 PAGE 1

NO.	ELEMENT	EXPECTED RATE	EXCEPTIONS	EXPLANATION
1.	Confidential Case History form is completed on all evaluation visits by the patient and clerical staff.	100%	If unable to obtain, 'NA' is noted in all blank spaces by clerk.	After two week interval, another Confidential Case History form should appear in chart.
2.	Medical Release form is completed by patient, clerk and clinician on all evaluation visits.	100%	Medical Release form to be signed by sponsor or guardian for patients with language barrier, other limitations, and/or medical conditions which would prevent understanding. a. Documentation of language barrier, other limitations, and/or medical conditions are noted in **Clinician's Comments section** by the clinician.	Clinician is responsible for making sure the medical release is completed in full.
3.	Epi Slip Verification is indicated by the clerical staff.	100%	None	EPI Slip verification is indicated by circling 'y' or 'n' on each clinic visit.
5.	Contact Verification	100%	1. If epi slip is circled yes, no need to verify.	The need for contact verification is indicated by the clinician in the **Chief Complaint section** or **Clinician's Comments section.**
	A. Clerical		1. If unable to verify, will note, sign and date in **Contact Verification section.**	If able to verify, the clerk fills out entire **Contact Verification section,** signs and dates.
	B. Clinicians		1. If patient has positive test results, no contact verification is needed. 2. Contact Verification is done for GC, syphilis, chlamydia, NGU & chancroid only according to the 30 or 90 day time frame. (90 for syphilis, 30 for GC, chlamydia, NGU and chancroid) 3. If unable to verify, will note, sign and date in **Contact Verification section.**	**If able to verify, clinician fills out entire Contact Verification section,** signs and dates.

AUDIT CRITERIA **QUALITY ASSURANCE**

QUANTITATIVE _____ QUALITATIVE X

COMMITTEE: SEXUALLY TRANSMITTED DISEASE DATE: 2-1-85

NO.	ELEMENT	EXPECTED RATE	EXCEPTIONS	EXPLANATION
4	**Continued**		4. If contact is in clinic at same time, clinician can verify by checking with other clinician about contact's infection.	
	C. Epi		1. If unable to verify, document reason why; date and signature is indicated in contact verification section.	If adequate information available to verify from outside agency, will fill out entire **Contact Verification,** sign and date it.
5	Reason for visit is indicated on each Medical form.	100%	There may be more than 1 reason for a visit, i.e., Tx. and Eval.	Indicated in **Clinic Visit section** with a circle byclerical and a check by clinician in: A. Evaluation (Eval.) B. Test of Cure (TOC) C. Treatment (Tx. D. Other Clinician's decision is used to determine patient's care.
6	Clinician elicits pertinent medical history and documents the following:	100%	1. Patient refuses, documented by clinician in **Clinician's Comments.** 2. Patient referred by other facility, documented in **Chief Complaint.**	
	A. Previous STDs		1. If the patient returns to clinic within 2 weeks to see MD or for tx., the chart may be filled in as follows: **'See previous history'** (or similar likeness to phrase) written in **Previous STDs section.**	A. *Does not* include current admission or TOC visit dx.
	B. Sex Preference		1. (See exception #1 above)	
	C. Sites Exposed		None	

AUDIT CRITERIA **QUALITY ASSURANCE**

QUANTITATIVE _____ QUALITATIVE X

COMMITTEE: SEXUALLY TRANSMITTED DISEASE DATE: 2-1-85 PAGE 3

NO.	ELEMENT	EXPECTED RATE	EXCEPTIONS	EXPLANATION
6	**Continued**			
	D. Current Medications		1. Illicit use of drugs, BCP's, or Vitamins need not correspond with medical release form. 2. Descrepancy of meds. will be noted in **clinician's** comments.	A. Must correspond with Medical Release B. If **'y'** is indicated, entire section must be written in red ink.
	E. Allergies		None	A. Must correspond with Medical Release. B. If **'y'** is indicated, entire must be written in red ink. D. If the patient is allergic to any meds that are listed in the *treatment section or other meds provided by the PHC*, first letter of the med is written in red in the **Treatment section.**
	F. LMP information		Males	
	G. Chief Complaint		None	
	H. Symptoms		1. If patient is returning the same day to see MD only, *do not repeat symptoms and do use same Medical form.* 2. If symptoms have not changed: **'See previous history'** or similar likeness is written in space.	A. Duration, character and frequency must be entered for *discharge, dysuria, itching and abdominal pain.* B. Character and duration must be entered for *rash, lesion and other.*
7	*Clinician performs examination, documents findings and then signs in **clinician's comments.***	*100%*	*1. Patient refuses, documented by clinician in **clinician's comments.*** *2. Patients returning for tx.* *3. If patient is returning to see MD only, refer to **Physician's Comments.***	

AUDIT CRITERIA **QUALITY ASSURANCE**

QUANTITATIVE _____ QUALITATIVE X

COMMITTEE: SEXUALLY TRANSMITTED DISEASE DATE: 2-1-85 PAGE 6

NO.	ELEMENT	EXPECTED RATE	EXCEPTIONS	EXPLANATION
10	Wet prep is given to all females for Trichomoniasis and Gardnerella.	100%	1. Dx. of trich. or gard. by other agency. 2. Test of cure visit for GC.	
11	KOH is given to all females for yeast and males with balanitis.	100%	1. Dx of Yeast by other agency. 2. Test of cure visit for GC.	
12	Ulcers, sores or suspected condyloma lata on genital or rectal area should be examined by darkfield microscopy.	100%	Physician's/clinician's discretion documented not to do.	Examination findings noted in **Physician's/Clinician's Comments.**
13	STAT RPR done on any patients with genital, rectal or oral lesion or skin rash.	100%	1. MD/clinician's discretion documented not to do. 2. No repeat within 30 days unless: history of element #12 changes.	A. Lesions or rash noted in exam findings. B. If RPR is positive, blood will be titered for VDRL at ODH. 1. If VDRL is positive at ODH, an FTA will be done if there is no previous reactive FTA or history of syphilis.
14	All tests initiated are documented in the record.	100%	FTA will only be circled, dated and initialed when specifically ordered by clinician (i.e., reactive RPR, rash, lesion and no past hx. of syphilis.	A. Clinician circles tests in lab section. B. *Other* is circled in **'STAT LAB"** section and type of test and results indicated.
15	All tests initiated have test results and date (if indicated) are posted.	100%	Dates and results meet requirements if recorded no later than: VDRL/RPR - 7 days from visit FTA, Chlamydia - 14 days from visit GC Culture - 8 days from visit Herpes Culture - 21 days from visit If ODH lab phones in results, clerk writes '(c)' on the date line and fills in date when slip arrives.	Dates and results are recorded as follows: RPR/VDRL: R - Reactive, NR - Non reactive STAT LAB: Pos - Positive, Neg - Negative All Others: Pos - Positive, Neg - Negative, NG - No growth Corresponding lab slips are attached to lab sheet.
16	Penicillin Sensitivity is indicated on all positive GC cultures.	100%	Lost cultures are documented on GC lab slip.	Indicated by circling 'y' or 'n'.

AUDIT CRITERIA **QUALITY ASSURANCE**

QUANTITATIVE _____ QUALITATIVE X

COMMITTEE: SEXUALLY TRANSMITTED DISEASE DATE: 2-1-85 PAGE 10

NO.	ELEMENT	EXPECTED RATE	EXCEPTIONS	EXPLANATION
17	**Continued** P. Epi-Rx NGU			Documented contact to NGU within 30 days.
	Q. Scabies			1. Clinical appearance of burrow and erythematous itchy papules. 2. Microscopic identification of mites, ova *and/or* feces.
	R. Trichomonas 1. Epi trich (males			Positive identification of trichomonads in wet mount. 1. Verified contact to female.
	S. Warts (Condylomata Accuminata)			1. Appearance of clinical symptoms as dx'ed by physician. 2. Nonreactive stat RPR.
	T. Yeast (male & female)			Positive KOH prep.
18	Treatment			Medication, dosage and frequency is appropriately checked according to dx.(es) made in **Clinical Impression section.**
	A. PID Evaluation		If pt. has discontinued tx. for longer than 24 hours, needs to be re-treated.	Clinicians may continue tx. from other facility or give meds. to supplement tx. from other facility.
	B. Wait for all test results		Physician's discretion documented to postpone tx.	Patient is treated according to test results already posted.
	C. No Apparent STD		Physician's discretion documented to treat 'other' infection.	No medication is given.
	D. Epi-Rx Syphilis		1. Allergic to drug. 2. Not given during pregnancy	A. Bicillin 2.4 mu IM B. Tetracycline 500mg. q.i.d. x 15 days. (Used if allergic to PCN.)

DATA RETRIEVAL AND DISPLAY **ELEMENT #: ____**

COMMITTEE: _____

DATE: _____

AUDIT TOPIC: _____

_____

CODE: **A - MEETS ELEMENT** **B - MEETS EXCEPTION** **C - VARIATION**

NAME	A	B	C	VARIATION	DEF

AUDIT SUMMARY

COMMITTEE: _____ DATE: _____ PAGE: _____

DEFICIENCY ATTRIBUTION, CAUSES AND RECOMMENDATIONS					
NO.	ELEMENT	TOTAL #	RATE IN %	CAUSES	RECOMMENDATIONS

QUALITY ASSURANCE REVIEW - CORRECTIVE ACTION FORM

COMMITTEE: _____ **DATE:** _____

Code: **1 - Teaching** **2 - Restructuring the Environment** **3 - Telling** **4 - Problem-Specific Solution**

ELEMENT #	ACCURACY RATE	CORRECTIVE ACTION				COMMENTS:
		1	2	3	4	

Submitted by: _____

APPENDIX B

CRITERIA FOR CHART AUDIT

Name of Patient _____ Chart Number _____

Name of Registration Clerk _____

Name of Clinician _____

Date of Patients Visit _____ Date of Audit _____

CRITERIA/STANDARD	MET	EXCEPTION	NOT APPLICABLE
REGISTRATION			
1. Name, address and telephone number of the patient	___	___	___
2. Age, race, marital status and sex of the patient	___	___	___
3. Emergency name and telephone number	___	___	___
4. Necessary laboratory slips	___	___	___
5. Signed consent	___	___	___
HISTORY			
1. Reason for attendance	___	___	___
2. Problem description (present symptoms, STD or symptoms in partners, past history of similar symptoms)	___	___	___
3. Past history of STD (type and dates)	___	___	___
4. Review of sexual activity	___	___	___
5. Females — date of LMP, aspects of LMP, birth control method	___	___	___
6. Drug allergies	___	___	___
7. Antibiotics/"other drug" usage (type, duration, and purpose)	___	___	___
PHYSICAL EXAMINATION			
1. Routine physical exam — females (skin/hair, lymph nodes, oral mucosa, external genitalia, vagina, cervix, bimanual, and anus)	___	___	___
2. Routine physical exam - males (skin/hair, lymph nodes, oral mucosa, penis, scrotum, anus)	___	___	___
3. Abnormal findings and description	___	___	___

COMMENTS: _____

_____

_____

_____

CRITERIA/STANDARD	MET	EXCEPTION	NOT APPLICABLE
LABORATORY			
1. Appropriate specimens obtained	___	___	___
2. Stat test results	___	___	___
Gram stain(s)	___	___	___
Darkfield	___	___	___
Wet mounts	___	___	___
RPR	___	___	___
Other	___	___	___
3. Reference Laboratory test results	___	___	___
Gonorrhea cultures	___	___	___
RPR/VDRL	___	___	___
Herpes, chlamydia cultures	___	___	___
Other	___	___	___
DIAGNOSIS			
1. Diagnosis identified	___	___	___
THERAPY			
1. Appropriate therapy	___	___	___
2. Instructions to patient	___	___	___
COUNSELING			
1. Specific Information on STD	___	___	___
2. Referred to D.I.S. for interviewing/ counseling	___	___	___
CONSULTATION			
1. Complication or non-STD problem	___	___	___
REFERRAL			
1. Complication or non-STD problem	___	___	___
FOLLOWUP			
1. Appointment given	___	___	___
2. History since last visit	___	___	___
3. Physical examination	___	___	___
4. Appropriate laboratory	___	___	___
SIGNATURE			
1. Signature in appropriate area	___	___	___

COMMENTS:_____

_____

_____

_____

APPENDIX C

CLINICIAN EVALUATION FORM

Name of Clinician _____

Name of Clinic _____

Evaluator _____ Date of Evaluation _____

Each clinician should be observed periodically to ensure the quality of patient services. The format below is a tool that can be used for recording such observations. After each objective, place a checkmark under the number that most closely fits the individual's performance. This tool can be used after observing one or several patients with the clinician.

0 - The clinician makes no specific attempt to accomplish the stated objective.
1 - The clinician makes an occasional attempt to accomplish the stated objective.
2 - The clinician accomplishes the stated objective.
3 - Not applicable.

INITIAL INTERACTION	**0**	**1**	**2**	**3**
Greets patient by name on initial interaction				
Introduces self and observer				
States reason observer present				
Establishes rapport with patient				
Determines reason for visit				

MEDICAL HISTORY	**0**	**1**	**2**	**3**
Obtains accurate STD history (includes date of last exposure, sexual preference, exposure sites, number of partners, symptomatology, and prior STD).				
Obtains accurate past/present medical history (includes allergies, current use of antibiotics or other medications, drug usage, contraception/LMP, and pregnancy).				
Obtains modified history appropriate for followup visit (symptomatology, sexual exposure, medication usage, partners' treatment, and other problems).				

COMMENTS: _____

_____

_____

PHYSICAL EXAMINATION	0	1	2	3
Assures patient is appropriately exposed during examination				
Gives appropriate instructions to patient				
Respects patients' rights to privacy/confidentiality				
Inspects skin/hair correctly				
Palpates nodes correctly				
FEMALE EXAM				
Examines external genitalia, perineum and anus				
Performs accurate speculum exam				
Examines vagina and cervix correctly				
Performs bimanual correctly				
Performs rectovaginal exam correctly				
Averages 15-20 minutes per uncomplicated exam				
MALE EXAM				
Examines penis correctly				
Palpates scrotum/scrotal contents correctly				
Inspects perianal area and anus correctly				
Averages 10-15 minutes per uncomplicated exam				
Examines oro-pharyngeal area correctly				
Performs an organized examination				

SPECIMEN COLLECTION/TRANSPORT/DIAGNOSIS	0	1	2	3
Collects *all* specimens appropriate for visit				
Correctly labels all specimens				
Collects and transports gonorrhea cultures correctly				
Collects Gram stains correctly				
Collects darkfield specimen correctly				
Collects wet mounts and/or pap smears correctly				
Collects other culture(s)and test(s) correctly				
Lab procedures performed accurately by clinician:				
Gram Stains				
Reading of GC cultures				
Darkfields				
RPRs				
Wet Mounts				

COMMENTS:_____

_____

DIAGNOSIS AND TREATMENT	0	1	2	3
Accurately records the appropriate diagnosis				
Selects appropriate treatment to be given				

COUNSELING AND EDUCATION	0	1	2	3
Clearly informs patient of his/her diagnosis				
Provides appropriate C & E pertaining to diagnosis				
Asks patient if he/she has questions				
Answers patient's questions appropriately				
Gives accurate medication instructions				
Determines patient's understanding of results/instructions				
Provides handouts when appropriate				
Discusses the importance of assuring sex partner(s) evaluation				
Discusses the importance/rationale of followup visit(s)				
Schedules followup visit, when indicated				
Indicates clinic availability for questions or problems				
Recommends lifestyle/sexual activity changes until follow-up completed				
Counsels on prevention of future infections/problems				
Remains sensitive to patient's concerns				
Maintains a relaxed manner throughout the interaction				
Maintains a nonjudgemental attitude throughout the interaction				
Maintains a professional demeanor throughout the interaction				

DOCUMENTATION	0	1	2	3
Legibly completes the medical records				
Thoroughly completes medical records				
Thoroughly documents information collected from patient				

REFERRALS/CONSULTATIONS	0	1	2	3
Consults with Disease Intervention Specialist (D.I.S.) or refers patients to him/her when indicated				
Consults with other appropriate STD staff (physician, lab, etc), or refers patients to them when indicated				
Refers patient to appropriate outside individual or agency (verbal and/or written) when indicated				

COMMENTS: _____

_____

APPENDIX D

REGISTRATION CLERK EVALUATION FORM

NAME OF REGISTRATION CLERK_____

NAME OF CLINIC_____

EVALUATOR_____ DATE OF EVALUATION_____

Each registration clerk should be observed periodically to ensure the quality of patient services. The format below is a tool that can be used for recording such observations. After each objective, place a checkmark under the number that most closely fits the individual's performance.

0 - The clerk makes no specific attempt to accomplish the stated objective.
1 - The clerk makes an occasional attempt to accomplish the stated objective.
2 - The clerk accomplishes the stated objective.
3 - Not applicable.

	0	1	2	3
Acknowledges the patient promptly upon his/her arrival at the registration area				
Greets the patient with professional cordiality				
Interacts courteously with the patient				
Asks only relevant questions for registration				
Respects patients' rights to privacy/confidentiality				
Provides understandable oral instructions on policy and flow				
Provides written handout describing clinic policy and flow				
Answers patients' questions appropriately (person to person or via telephone conversation)				
Completes necessary forms efficiently				
Records all necessary information on daily logs, etc.				
Retrieves medical records/information efficiently				
Routinely checks the "expected-in" file				
Consults with clinic manager or appropriate individual when indicated				

COMMENTS:_____

APPENDIX E

PATIENT INFORMATION HANDOUT

Patient information sheets or pamphlets given to patients when they enter the clinic serve several helpful purposes. Anxiety can be eased by letting patients know what to expect in the beginning. The information the sheet provides can stimulate interactions by helping to establish rapport, enhance communication, and encourage patients to ask questions.

Many clinics already have excellent information pamphlets available for their patients. For the facility needing to develop a pamphlet, the sample which follows should be helpful. It was developed into a generic model using the excellent handout provided by the STD Clinic in Fairbanks, Alaska. Regardless of the type of form developed, a printed sheet or a folding pamphlet, important information should include: (1) the name of the clinic, its address, and its telephone number, (2) an assurance of confidentiality, (3) clinic hours, (4) the registration process, (5) clinic flow, (6) the examination procedure, facts about diagnosis and treatment, (7) the need for followup, (8) any fees for services, (9) the importance of sex partner referral, and (10) an invitation to ask questions or submit ideas on improving services.

The sheet or pamphlet may allow for the registration clerk to write the patient's number at the top. This can eliminate the need to hand out number cards that can get lost or misplaced. The information handout can also serve as a call back sheet, eliminating the need to give out duplicate forms after the patient has been examined.

By providing this information to patients, clinics can reduce anxiety, expedite clinic flow, and increase the quality of services provided.

COUNTY HEALTH CENTER
800 Airport Way
Telephone: 555-1776

SEXUALLY TRANSMITTED DISEASE CLINIC

Monday	8:00 p.m. - 4:00 p.m.
Tuesday	11:00 a.m. - 7:00 p.m.
Wednesday	8:00 a.m. - 4:00 p.m.
Thursday	11:00 a.m. - 7:00 p.m.
Friday	8:00 a.m. - 4:00 p.m.

PATIENT INFORMATION SHEET

Welcome to the County Health Center's Sexually Transmitted Disease (STD) Clinic. We hope that the information provided in this sheet may answer some of your questions.

All services you receive are provided free of charge by the State and County Health Departments. The patient identification form you were given to complete will be used to make up your medical record. Please be sure to give a current address and telephone number (if we need to reach you about a positive test, it is important that we be able to). EVERYTHING contained in your record is CONFIDENTIAL. No information will be released without your written consent. After you have filled out this form, you will be given a number and asked to have a seat. All patients who arrive during clinic hours will be seen. Since this is a walk-in clinic, your patience while waiting is appreciated.

The clinician will call you by your number, *not your name*. Numbers are not always called in order. You will either see a physician or a nurse. When you are in the exam room you will be asked a few questions about the reason for your visit and about your health history. Also, blood may be drawn from your arm to test for syphilis if you have not been tested recently. The clinician will then do a brief examination of your genitals. During this exam, a test for gonorrhea will be taken from any opening that has been possibly exposed to a sexually transmitted disease. If a discharge is present, an immediate exam of the discharge under the microscope may be possible. The results of this test takes only a few minutes, but all other test results may take several days.

Treatment may be obtained for some infections during this visit. For other infections, treatment will be delayed until the clinic receives the laboratory results. If you are given an antibiotic, you will be asked to wait for approximately 20 - 30 minutes—please do so. This is to make sure that you do not have a severe reaction to the medication. If you are given medicine to take with you, make sure that you clearly understand when and how to take it before you leave. Be sure that you alone take *all* of the medicine. You will receive just enough to cure you, so take it all as instructed. Your symptoms may go away before you finish. This is a sign that the medicine is working, but not that you are cured.

If you do not receive treatment during this visit, you will be asked to call for your test results. At this time, you will be advised if you need to return for treatment and/or any follow-up tests. Treatment will only be given during STD Clinic hours. You may obtain your own, and only your own test results by calling 555-1776 between the following hours:

If you were seen in:	*Call*:	
Monday's Clinic	Thursday	2:00 p.m. - 5:00 p.m.
Tuesday's Clinic	Friday	12:00 noon - 3:00 p.m.
Wednesday's Clinic	Monday	12:00 p.m. - 3:00 p.m.
Thursday's Clinic	Tuesday	2:00 p.m. - 5:00 p.m.
Friday's Clinic	Wednesday	12:00 noon - 3:00 p.m.

If you are treated for certain sexually transmitted diseases, you will receive the support necessary to help your sex partner(s). This is important because (1) their health is in jeopardy and very much in your hands; (2) they pose a risk to you for getting the same disease again; and (3) they may have other sexually transmitted diseases (there are over 25) that by examining them we may be able to assure you are totally cured.

The CLINIC IS HERE TO SERVE YOU. We need your help to serve you in the best way possible. Please ask questions. If we say or do something that upsets you, please let us know so that we can improve our services.

APPENDIX F

MEDICAL RECORD INFORMATION

A. Identifying Information

1. Name
   Complete name is needed to differentiate patients with same or similar names.
2. Identification Number
   The number should be unique to each patient's medical record.
3. Address
   Should be complete with apartment number (if any) and zip code.
4. Phone Number(s)
   The number where the patient prefers to be contacted should be noted.
5. Date of Birth
6. Sex
7. Marital Status
8. Race/Ethnic Origin
9. Next of Kin or Person to be Contacted in an Emergency
   The patient may wish to list the name, address, and phone number of a relative or friend.
10. Consent for Examination and Treatment
    When the community standard of practice calls for written consent for outpatient management, a consent form should be signed, witnessed, and included in the chart.

B. Clinical History

1. Reason(s) for Visit
2. A Description of Symptoms
   Symptoms and their duration should be noted, as well as relationship to sexual intercourse and urination, prior history of similar problems, and the history of similar or other problems in a sex partner.
3. Sexual History
   Last sexual exposure, exposure sites*, number of partners in previous month*, sexual preferences*, sexual practices*, use of condoms, and sexual partner's health problems should be included.
4. History of Recent or Current Medications
   Use of systemic or topical antibiotics should be emphasized.
5. Drug Allergies
   Name of drug, type of reaction, and date.
6. Contraception and Menstrual Cycle
   Determine the date of the last menses, unusual aspects of the last menses, and use of a contraceptive method.
7. Past History of STD
   Indicate all prior STD and treatment with dates.

C. Physical Examination

This should be standardized to encourage clinicians to perform a complete genital evaluation (see Appendix C).

D. Laboratory Evaluations

The record should list all tests the clinic can do and those sent to another laboratory.

E. Assessment/Diagnosis

F. Treatment Plan and Followup

G. Examiner and Interviewer

Each clinician and interviewer should sign the medical record legibly.

* Caution should be observed on including certain aspects of medical/sexual history (i.e., number of sexual partners in the past month, specific exposure sites, sexual preference, and sexual practices) that the confidentiality statute of the jurisdiction is sufficiently strong to avert the reasonable possibility that the record could be obtained through a subpoena. If the records are not so protected, this information could leave patients vulnerable in civil or criminal court proceedings.

APPENDIX G

MEDICAL RECORD EXAMPLES

FEMALE — **STD CLINIC MEDICAL RECORD** — YEAR _____ Disease: GC SYPH OTHER

DATE

NAME: LAST FIRST MI | DATE OF BIRTH | AGE | MARITAL STATUS ☐S ☐M ☐SEP ☐DIV ☐W | SSN

ADDRESS APT # | PHONE HOME _____ WORK _____ | ETHNIC GROUP ☐BL ☐HISP ☐NAI ☐WH ☐ORIENT ☐OTHER

CITY STATE ZIP CODE

REASON FOR VISIT
- ☐ Sx Self
- ☐ Epi GC
- ☐ Epi Syphilis
- ☐ Sex Partner Referral (Comment)
- ☐ Agency/PMD Referral (Comment)
- ☐ Other (explain)
- ☐ Comments:
- ☐ Routine Exam
- ☐ TOC
- ☐ Screening

SYMPTOMS

	YES	NO	SITE	DURATION
Discharge	☐	☐		
Dysuria	☐	☐		
Lesion	☐	☐		
Rash	☐	☐		
Itch	☐	☐		
Pain	☐	☐		
Other	☐	☐		

PRIOR STD

	YES	NO	# TIMES	LAST TIME
Gonorrhea	☐	☐		
Syphilis	☐	☐		
NSV	☐	☐		
Herpes	☐	☐		
Other (explain)	☐	☐		

LAST MENSTURAL PERIOD Date _____ ☐ Abnormal ☐ Normal (Comment)

CONTRACEPTION ☐ NONE ☐ IUD ☐ Diaphragm ☐ Foam ☐ Pill ☐ Other

MEDICINE/DRUG USE Past 30 Days ☐ Yes ☐ No — Drug _____ For _____ Last Dose _____

ALLERGIES

	YES	NO
Penicillin	☐	☐
Other	☐	☐

Describe:

SEXUAL HX: # Partners Past 3 Months _____

PREGNANT: ☐ Yes ☐ No Due Date _____

ASSESSMENT

	YES	NO	COMMENT
Vaginal (Abnormal)	☐	☐	
Discharge	☐	☐	
☐ Scant ☐ Moderate ☐ Profuse			
☐ Clear ☐ Purulent			
Cervix (Abnormal)	☐	☐	
Exudate	☐	☐	
☐ Scant ☐ Moderate ☐ Profuse			
☐ Clear ☐ Purulent			
Bimanual (Abnormal)	☐	☐	
Cx Motion Tender	☐	☐	
Adnexal Tender	☐	☐	
Abdomen (Abnormal)	☐	☐	
Lesion	☐	☐	
Lymph Nodes (Abnormal)	☐	☐	
Rash	☐	☐	

Temperature (oral) _____ Last Douche _____

Comments:

LABORATORY

STAT	POS	NEG	UNSAT
☐ Cx Gram Stain	☐	☐	☐
☐ Trich	☐	☐	☐
☐ Yeast	☐	☐	☐
☐ Darkfield	☐	☐	☐
☐ RPR	☐	☐	☐
☐ Other _____	☐	☐	☐
PENDING			
☐ Cx Culture	☐	☐	☐
☐ R Culture	☐	☐	☐
☐ Th Culture	☐	☐	☐
☐ RPR Titer _____	☐	☐	☐
☐ MHA-TP	☐	☐	☐
☐ Herpes	☐	☐	☐
☐ Chlamydia	☐	☐	☐
☐ Other _____	☐	☐	☐

IMPRESSIONS ☐ No STD
- ☐ Gonorrhea
- ☐ NSV
- ☐ Herpes
- ☐ Other _____
- ☐ PID
- ☐ Crabs
- ☐ Scabies
- ☐ Molluscum
- ☐ Syphilis Stage _____
- ☐ Warts

Signature/Title _____

DIAGNOSIS:

PHYSICIAN:

THERAPY DESCRIBE
- Ampicillin _____
- APPG _____
- Probenecid 1gm. ☐ Yes ☐ No
- Tetracycline _____
- Bicillin _____
- Other _____

COUNSELLING

Therapy: ☐ Administration ☐ Side Effects

Follow-up: ☐ TOC _____ Date ☐ Rescreening _____ Date ☐ Revisit _____ Date

Prevention: ☐ Partner Referral ☐ Risk Reduction ☐ Respond To Disease Suspicion

REFERRED TO ANOTHER AGENCY Where: _____

REFERRED TO EPI ☐ Yes ☐ No Epi Worker _____

NOTES

H-2629

STD-10 NOV 81

MALE

DATE

STD CLINIC MEDICAL RECORD

YEAR

Disease: GC SYPH OTHER

NAME LAST FIRST MI | DATE OF BIRTH | AGE | MARITAL STATUS S M SEP DIV W | SEX

ADDRESS APT # | PHONE HOME WORK | ETHNIC GROUP BL HISP NAT WH ORIENT OTHER

CITY STATE ZIP CODE

REASON FOR VISIT

- ☐ Sx Self
- ☐ Epi GC
- ☐ Epi Syphilis
- ☐ Sex Partner Referral (Comment)
- ☐ Agency/PMD Referral (Comment)
- ☐ Other (explain)
- ☐ Comments
- ☐ Routine Exam
- ☐ TOC
- ☐ Rescreening

SYMPTOMS

	YES	NO	SITE	DURATION
Discharge	☐	☐		
Dysuria	☐	☐		
Lesion	☐	☐		
Rash	☐	☐		
Itch	☐	☐		
Pain	☐	☐		
Other	☐	☐		

PRIOR STD

	YES	NO	# TIMES	LAST TIME
Gonorrhea	☐	☐		
Syphilis	☐	☐		
NGU	☐	☐		
Herpes	☐	☐		
Other (explain)	☐	☐		

Comments

SEXUAL HISTORY

Partners Past 3 Months

Male # Female

ALLERGIES

	YES	NO
Penicillin	☐	☐
Other	☐	☐

Describe

MEDICINE/DRUG USE

Past 30 days ☐ Yes ☐ No

Drug

For

Last Dose

ASSESSMENT

	YES	NO	COMMENT
Lesion	☐	☐	
Rash/Nodes	☐	☐	
Scrotum (Abnormal)	☐	☐	
Rectum (Abnormal)	☐	☐	
Discharge	☐	☐	

☐ Scant ☐ Moderate ☐ Profuse

☐ Clear ☐ Purulent

Last Void Hours

Comments

LABORATORY

STAT	POS	NEG	UNSAT
☐ U Gram Stain	☐	☐	☐
☐ R Gram Stain	☐	☐	☐
☐ Darkfield	☐	☐	☐
☐ RPR	☐	☐	☐
☐ Other	☐	☐	☐
PENDING			
☐ U Culture	☐	☐	☐
☐ R Culture	☐	☐	☐
☐ Th Culture	☐	☐	☐
☐ RPR Titer	☐	☐	☐
☐ MHA-TP	☐	☐	☐
☐ Herpes	☐	☐	☐
☐ Other	☐	☐	☐

IMPRESSION ☐ No STD

☐ Gonorrhea ☐ Warts ☐ Molluscum

☐ NGU ☐ Crabs ☐ Syphilis Stage

☐ Herpes ☐ Scabies

☐ Other

Signature/Title

THERAPY DESCRIBE

Ampicillin

APPG

Probenecid 1 gm. ☐ Yes ☐ No

Tetracycline

Bicillin

Other

DIAGNOSIS

Physician

REFERRED TO ANOTHER AGENCY

Where

COUNSELLING

Therapy: ☐ Administration ☐ Side Effects

Follow-up: ☐ TOC Date ☐ Rescreening Date ☐ Revisit Date

Prevention: ☐ Partner Referral ☐ Risk Reduction ☐ Respond To Disease Suspicion

REFERRED TO EPI ☐ Yes ☐ No Epi Worker

NOTES

STD-9 H-2638

Record Closed By Date

FEMALE

Last Name | First | Middle | Age / Birth Date | Marital Status: Sing Mar Sep Wid Div | Race: W B S A I O | Clinic #

Street | Phone | County

Patient # | Date of Visit | Form # | Reg. Time | Emp. Address or Phone

No Yes ___ ___ Partner in Clinic today. If yes, enter clinic number

History

REASON FOR VISIT

- ___ Volunteer Because of Symptoms
- ___ Seeks Checkup
- ___ Sexual Partner Referral (Specify disease) Disease ___
  - ___ H.D. Patient # ___
  - ___ Patient ___
- ___ Post Treatment Follow-up
- ___ Rx Pos. GC Culture ___
- ___ Treatment Syphilis ___
- ___ Referral from another Facility (specify) ___
- ___ Other (specify) ___

STD ELSEWHERE

Yes	No		Last Episode
___	___	GC	___
___	___	Vaginitis	___
		___ Trich ___ Yeast ___ Other	
___	___	PID	___
___	___	Syphilis	___
		When	___
		Where	___
___	___	Herpes	___
		___ Oral ___ Genital	
___	___	Other ___	___

ALLERGIES

No Yes

___ ___ Penicillin

___ ___ Other drug (specify)

___

SEXUAL

Last Exposure ___

PREFERENCE ___ Female ___ Male ___ Both

Oral Sex ___

Number of Partners

Last 30 days ___

OTHER

Yes

___ Abnormal LMP

LMP (date of onset) ___

___ Pregnant?

___ Douche last 24 hours

___ Pap Smear Last Year?

___ Contraception (specify method) ☐

___

___ Antibiotics within the last 2 weeks? ___ Prasc ___ Other

BLOOD PRESSURE ___

SYMPTOMS

No	Yes		Duration
___	___	Vaginal Discharge	___
___	___	Dysuria	___
___	___	Sores	___
___	___	Itching (specify location)	___
		___	
___	___	Condyloma	___
___	___	Rash	___
___	___	Abdominal Pain Cramps	___
___	___	Abnormal Vaginal Bleeding	___
___	___	Other ___	___

PHYSICAL EXAM Description

No	Yes	
___	___	Discharge - Vaginal
___	___	Lesion - Site ___
___	___	Condyloma
___	___	Rash
___	___	Abnormal Cervix
___	___	Abdominal Tenderness
___	___	Adnexal Tenderness ☐ R ☐ L ☐ Both
___	___	Pain on Cervical Motion (Cervical Tenderness)
___	___	Other ___

IMMEDIATE LABORATORY EXAMINATIONS

Performed	Neg	Pos	Extra Only	PMN'S < 4	PMN'S ≥ 4
___ Gramstain	___	___	___	☐	☐
___ Darkfield	___	___	___		
___ RPR	___	___	___ MIN		
___ KOH	Neg	YST	DERM TV		
___ Wet Mount	Neg	Trich	YST CV		
___ Other ___	___				

OTHER LABORATORY TESTS

Performed	Neg	Pos	Unsat
GC Culture			
___ Cervical	___	___	___
___ Rectal	___	___	___
___ Throat	___	___	___
___ Other ___	___	___	___
___ PPNG	___	___	___
Chlamydia Culture			
___ Cervical	___	___	___
Trichomonas Culture			
___ Vaginal	___	___	

Performed	Neg	Pos	Titre
___ RPR	___	___	
___ FTA-ABS	___	___	BL
Herpes Culture			Unsat
___ Site ___			___
Typing			1 2
___ Site ___			___
Typing			1 2
___ Pap			
___ Other ___			

DIAGNOSIS

Treatment Given by:

- ( ) PCN ___
- ( ) TCN ___ DIS. TIME ___
- ( ) ERY ___
- ( ) AMP ___
- ( ) FLAGYL ___ ___ Rx for Partner
- ( ) other ___
- ( ) No Rx ___

PLAN

- ___ Referred to ___
- ___ Sexual Partner Referral Interview ☐☐☐
- ___ Research Project ☐☐☐
- ___ Other

Clinician

Reviewer

MALE

Last Name | First | Middle | Age / Birth Date | Marital Status: Sng Mar Sep Wid Div | Race: W B S A I O | Clinic #

Street | Phone | County

Patient # | Date of Visit | Form # | Reg. Time | Emp. Address or Phone

No Yes
___ ___ Partner in Clinic today. If yes, enter clinic number ___

REASON FOR VISIT

- ___ Volunteer Because of Symptoms
- ___ Seeks Checkup
- ___ Sexual Partner Referral (Specify disease) Disease ___
  - ___ H.D Patient # ___
  - ___ Patient ___
- ___ Post Treatment Follow-up
- ___ Rx Pos. GC Culture ___
- ___ Treatment Syphilis ___
- ___ Referral from another Facility (specify) ___
- ___ Other (specify) ___

STD ELSEWHERE

	Yes	No	Last Episode
GC	___	___	___
NGU	___	___	___
Syphilis	___	___	___
When			___
Where			___
Herpes	___	___	___

___ Oral ___ Genital

___ Other ___ ___

HISTORY

ALLERGIES

No Yes
___ ___ Penicillin
___ ___ Other drug (specify) ___

SEXUAL

Last Exposure ___
PREFERENCE ___ Female ___ Male ___ Both
Oral Sex ___
Number of Partners
Last 30 days ___

OTHER

Yes
___ Contraception (specify method) Regularly used ☐ ___
___ Antibiotics within the last 2 weeks? ___ Presc ___ Other
BLOOD PRESSURE ___

SYMPTOMS

No	Yes		Duration
___	___	Urethral Discharge	___
___	___	Rectal Discharge	___
___	___	Dysuria	___
___	___	Sores	___
___	___	Itching	___
___	___	Condyloma	___
___	___	Rash	___
___	___	Other ___	___

PHYSICAL EXAM

No	Yes		Description
___	___	Discharge Urethral	
___	___	Lesion Site ___	
___	___	Condyloma	
___	___	Rash	
___	___	Inguinal nodes	
___	___	Other ___	

IMMEDIATE LABORATORY EXAMINATIONS

Performed	Neg	Pos	Extra Only	PMN'S < 4	PMN'S > 4
___ Gramstain (Urethral)	___	___	___	☐	☐
___ Gramstain ___	___	___	___	☐	☐
___ Darkfield	___	___	___		
___ RPR	___	___	___ MIN		
___ KOH	___ Neg	YST	DERM	TV	
___ Other (specify)					

OTHER LABORATORY TESTS

Performed	Neg	Pos	Unsat
___ GC Culture			
___ Urethral	___	___	___
Rectal	___	___	___
Throat	___	___	___
Other ___	___	___	___
___ PPNG	___	___	___
Chlamydia Culture			
___ Urethral	___	___	___
Trichomonas Culture			
___ Urethral	___	___	

Performed	Neg	Pos	Titre
___ RPR	___	___	
___ FTA-ABS	___	___	BL

Herpes Culture	Unsat
___ Site ___	___ ___ ___
Typing	1 2
___ Site ___	___ ___ ___
Typing	1 2
___ Other ___	

DIAGNOSIS

Treatment Given by

( ) PCN ___
( ) TCN ___ DIS TIME ___.
( ) ERY ___
( ) AMP ___
( ) FLAGYL ___
( ) other ___
( ) No Rx

PLAN

___ Referred to ___
___ Sexual Partner Referral Interview ☐☐☐
___ Research Project ☐☐☐
___ Other

Clinician

Reviewer

FEMALE

NAME DATE NO.

REASON(S) FOR VISIT:
☐ Contact to _____ Established _____
☐ Symptoms ☐ Surveillance
☐ Required Test ☐ Partner Problems
☐ MD Referral _____
☐ Other _____

MEDICATIONS:
☐ Antibiotics (2 wks.) _____

PROBLEM(S): ☐ None

NO	YES	DESCRIBE
☐ Vaginitis	☐	
☐ Lower Abdominal Pain	☐	
☐ Other	☐	

LMP _____ ☐ Norm. ☐ Abnl.

SEX HISTORY:
Last exposure _____ No. _____
Preference: ☐ Male ☐ Female ☐ Both

ALLERGIES
☐ No ☐ Yes
☐ Asthma and/or Hay Fever

PREVIOUS STD: ☐ None
☐ GC ☐ Syphilis _____ Rx _____
☐ NSV ☐ Trich ☐ Yeast
☐ Other _____ Last Blood Test _____

CONTRACEPTION:
☐ None ☐ Pill ☐ IUD ☐ Other _____

PHYSICAL EXAM:

NO	YES	DESCRIBE
☐ Vulva abnl	☐	
☐ Vagina abnl	☐	
☐ Cervix abnl	☐	
☐ Discharge	☐	
☐ Lesions	☐	
☐ Rash	☐	
☐ Abnl Nodes	☐	
☐ Other	☐	
☐ Bimanuel done	☐	
☐ Norm. ☐ Abnl		
☐ Other Exams	☐	

LAB:
☐ KOH _____
☐ Saline _____
☐ VIP _____
☐ C Culture _____
☐ R Culture _____
☐ O Culture _____
☐ RPR _____ ☐ DF _____
☐ VDRL _____
☐ Herpes _____
☐ Pap _____
☐ Pregnancy _____
☐ Other _____

IMPRESSIONS:
☐ No Disease
☐ GC
☐ Trich
☐ Yeast
☐ NSV
☐ Warts
☐ Herpes
☐ Crabs
☐ Scabies
☐ PID
☐ Syphilis
☐ Contact _____
☐ Suspect _____
☐ Other _____

THERAPY: _____

FOLLOW UP:
☐ Call for results
☐ Return _____
☐ Referral _____

INTERVIEW: _____
EXAMINER: _____
REVIEWER: _____

DATE NO.

DATE NO.

MALE

NAME NO.

REASON(S) FOR VISIT:
- ☐ Contact to _____ Established _____
- ☐ Symptoms ☐ Surveillance
- ☐ Required Test ☐ Partner Problems
- ☐ MD Referral _____
- ☐ Other _____

SEX HISTORY:
Last exposure _____
Number (past month) _____
Preference: ☐ Male ☐ Female ☐ Both

MEDICATIONS:
- ☐ Antibiotics (2 wks.) _____

ALLERGIES:
Penicillin: ☐ No ☐ Yes
- ☐ Other _____
- ☐ Asthma and/or Hay Fever

PROBLEM(S): ☐ No Symptoms

NO	YES	DESCRIBE
☐ Discharge	☐	
☐ Dysuria	☐	
☐ Other	☐	

PREVIOUS STD: ☐ None
- ☐ GC ☐ Syphilis _____ Rx _____
- ☐ NSU Last Blood Test _____

PHYSICAL EXAM: ☐ Not Done (why) _____

NO	YES	DESCRIBE
☐ Skin abnl	☐	
☐ Abnormal Nodes	☐	
☐ Scrotum abnl	☐	
☐ Penis abnl	☐	
☐ Urethral Discharge	☐	
☐ Mucoid	☐ Mucopurulent	☐ Purulent
☐ Little	☐ Moderate	☐ Heavy
☐ Other Exams		

LAB:
- ☐ Urethral Smear _____
- ☐ U Culture _____
- ☐ O Culture _____
- ☐ R Culture _____
- ☐ RPR _____ ☐ DF _____
- ☐ VDRL _____
- ☐ Herpes _____
- ☐ Other _____

REVIEWER: _____

IMPRESSIONS: ☐ No Disease
- ☐ GC
- ☐ NSU
- ☐ Warts
- ☐ Herpes
- ☐ Crabs
- ☐ Scabies
- ☐ Syphilis
- ☐ Contact _____
- ☐ Suspect _____
- ☐ Other _____

THERAPY: _____

FOLLOW-UP:
- ☐ Call for Results
- ☐ Return _____
- ☐ Referral _____

INTERVIEW: _____

EXAMINER: _____

DATE	NO.	DATE	NO.

APPENDIX H

PROCEDURE FOR PURGING MEDICAL RECORDS

Clinic procedures for purging STD medical records must be consistent with existent medical record retention laws and regulations. An effective STD Control program requires that medical records be handled in a manner that assures protection from unauthorized disclosure. Most of the states have recognized this exceptional need by enacting sexually transmitted disease confidentiality laws. STD records which are not pertinent to future medical care and have exceeded the required retention period should be destroyed.

Medical record purging is facilitated by coding medical charts according to diagnosis and the month and year of last visit. Clinics which do not have a record file coding system should also purge on a regular basis. Specific information may be assigned to a color of tape or a number, which is then attached to, or written on, the edge of the record folder. This information may be updated by taping the new color or number over the outdated code.

Syphilis records may be color coded to distinguish them from nonsyphilis records. The charts belonging to patients last seen during the same year, should bear the same color or number. Additionally, the month of the last visit may be color or number coded alongside the year code.

Example A (Clinics with record filing codes):

1. The medical records file is purged of all nonsyphilis records older than one year and purged records are stored away from the main clinic area until the legal retention period expires.
2. Syphilis records (or records with any positive syphilis test) are not purged.
3. At the beginning of each month, the nonsyphilis records for the same month of the previous year are purged and stored with previously purged records.
4. As patients return to clinic within a year of their last visit, the month color or number code is changed. Thus, records remain in the active file for 1 year after their last visit.

Example B (Clinics without record filing codes):

1. Each year all clinic records should be reviewed.
2. If the last STD visit was less than 1 year from the date of this review, the record is returned to the current file.
3. All syphilis records (or any records with a positive syphilis test) are returned to the current file.
4. Other records (nonsyphilis, older than one year) are purged. Purged records are stored away from the main record area until the legal retention period expires.

NOTE: Some medical facilities continue to chart STD visits in the same medical record with other non-STD visits. With this system, protecting the records of STD patients from unauthorized disclosure is more difficult.

Since many non-STD medical problems are not amenable to periodic purging, purging of the STD component may not be possible.

APPENDIX I

EQUIPMENT AND SUPPLIES FOR STD EXAMINATION ROOMS

A. Furniture

1. Examination table with stirrups.
2. Sink with water source.
3. Writing table.
4. Patient chair.
5. Clinician chair (swivel type).
6. Supply storage cabinet.
7. Examination lamp (moveable arm type).
8. Trash can.

B. Physical Examination Equipment and Supplies

1. Vaginal specula (stainless steel or disposable; small, medium, and large sizes in ratio of 1:5:1; also Pederson/virginal type).
2. Anoscopes (stainless steel or disposable).
3. Magnifying glass.
4. Forceps (small straight type and ring type).
5. Flashlight with fresh batteries.
6. Thermometer.
7. Stethoscope.
8. Sphygmomanometer.
9. Otoscope/ophthalmoscope.
10. Gloves (disposable, various sizes).
11. Tongue depressors.

C. Specimen Collection Supplies

1. Scalpel and #11 blades.
2. Glass slides (1" by 3" with frosted end).
3. Cover slips (1" by 1").
4. Gauze pads (sterile, 2" by 2" and/or 4" by 4").
5. Normal saline (sterile).
6. Cotton balls and adhesive tape.
7. Isopropyl alcohol.
8. Tourniquets.
9. Blood collection tubes ("red top," evacuated, nonsterile, various sizes).
10. Blood collection tube holders.
11. Test tube rack.
12. Venipuncture needles (20/21 gauge; 1 1/2").
13. Syringes (5 ml).
14. Needles (18, 21, 23 gauge).
15. Urine specimen containers.
16. Cotton-tipped applicators (sterile).
17. Calcium alginate swabs (or bacteriologic platinum wire loop and source for heat sterilization).
18. Sterile lubricant.
19. Test tubes.
20. Potassium hydroxide (10% solution).
21. Culture plates with a recommended selective medium for gonorrhea (Martin-Lewis, Modified Thayer-Martin, or New York City media).
22. Candle jar with candle and matches or special plastic bags with carbon dioxide generating tablets.
23. Tubes of Cary-Blair transport medium for stool collection.

D. Miscellaneous Supplies

1. Examination table paper.
2. Disposable paper sheets and/or patient dressing gowns.
3. Paper towels.
4. Soap.
5. Sanitary napkins and tampons.

APPENDIX J

MANAGEMENT OF ACUTE REACTIONS TO PENICILLIN AND OTHER DRUGS

ANAPHYLAXIS

Anaphylactic reactions are reported most frequently following therapy with antibiotics, particularly with the penicillins and cephalosoprins. Profound shock and severe respiratory distress are the hallmarks of severe anaphylactic reactions. The clinical presentation of an anaphylactic reaction depends on the portal of entry of the antigen or foreign substance, the amount absorbed, the rate of absorption, and the degree of hypersensitivity of the patients. For example, ingestion of an antigenic substance may produce gastrointestinal symptoms such as nausea, vomiting, abdominal cramping, and diarrhea, which proceed more severe symptoms; in contrast, following an antigenic injection, a severe life-threatening shock and respiratory distress may occur without preceding symptoms. The range of signs and symptoms associated with anaphylactic reactions may cover a wide range of severity.

These reactions represent true medical emergencies, therefore, prompt recognition is crucial. An immediate response and appropriate management will increase the likelihood of the best possible outcome.

At the first suspicion of a drug reaction, a clinician immediately should use a predetermined system to notify clinic staff of the emergency situation and its location. The clinician should remain with the patient and initiate basic supportive measures. Designated staff should respond quickly and assist in the emergency. Each staff member should have a designated task with one staff member designated to call the ambulance once the need is established. A preselected clinician should be in charge and should make all therapeutic decisions, according to approved protocols.

The maintenance of an airway and adequate ventilation are first priorities in management of patients with anaphylactic reactions. Epinephrine is the agent of choice for treating the acute manifestations of anaphylaxis such as bronchoconstriction and hypotension.

Management

1. Mild Anaphylactic Reaction or Urticaria Alone
   a. Epinephrine, 1:1000, 0.3 - 0.5 ml, SQ or IM
   b. Diphenhydramine, 25 - 50 mg, IM
   c. If the response is adequate (decreasing pruritus and lessening of the rash), prescribe (for adults) an antihistamine such as diphenhydramine (25 - 50 mg), chlorpheniramine (4 mg), or promethazine (12.5 mg), to be taken 3-4 times a day as needed.
   d. If the response is inadequate or if other signs or symptoms occur, continue supportive and therapeutic measures and transport the patient to an emergency facility.
2. Less Severe Anaphylactic Reaction (without hypotension or loss of consciousness)
   a. Epinephrine, 1:1000, 0.3 - 0.5 ml, SQ or IM
      Repeat doses may be given at 5 to 10 minute intervals as needed.
   b. Diphenhydramine, 25 - 50 mg, IM
      This agent does not play a significant role in the management of life- threatening emergencies but may be useful after the patient is stabilized.
3. Severe Anaphylactic Reactions
   a. Place patient in a supine position with the legs elevated.
   b. Maintain an adequate airway and ventilation. An oral airway may be of benefit, if not, an endotrachial tube may be needed.
   c. Assess the vital signs and status of the patient.
   d. Administer oxygen and other pharmacologic agents as per emergency protocol.
   e. Periodically reassess the patient's status.
   f. Start an intravenous line and give epinephrine, 1:1000, 0.5 - 1.0 m. in 10 cc of saline, IV. Repeat every 5 - 15 minutes as necessary. If no venous access, epinephrine may be given through the endotracheal tube.
   g. For severe wheezing (bronchospasms) without shock, give aminophylline, 500 mg IV, over 10 - 20 minutes.

h. Transport the patient to an emergency facility.
i. All emergency procedures and drugs provided should be accurately recorded on an appropriate form that will accompany the patient to an emergency facility. (A copy should be kept in the patients medical record at the STD Clinic).

PROCAINE REACTIONS

Procaine reactions are not allergic reactions. Two types of reactions following procaine injection have been described. The first type of reaction involves extreme anxiety. Some patients experience disorientation, hallucinations, and agitation. Such reactions are generally the result of direct procaine toxicity and usually resolve within 15 - 30 minutes. The second type of reaction is similar, but hyperventilation, hypertension, tachycardia, and vomiting may occur. Hypotension may occur in severe cases. This reaction is usually due to inadvertent intravenous injection of procaine.

Management

1. Establish that the patient is not hypotensive, not in respiratory distress, and does not have allergic manifestations.
2. Place the patient in a supine position. Use physical restraint if necessary.
3. Provide calm and continuous verbal reassurance and any supportive care necessary.

CHARACTERISTICS OF PENICILLIN ALLERGIC REACTIONS

Immediate reaction	
Time:	Characteristics:
2 - 20 minutes after administration	Diffuse (giant) urticaria; laryngeal edema; wheezing, rhinitis; hypoxia; hypotension; tachycardia; nausea; vomiting; abdominal pain; diarrhea, rigors; vascular collapse

Accelerated reaction	
Time:	Characteristics:
30 minutes to 48 hours after administration	Urticaria; laryngeal edema (infrequently)

Delayed reaction	
Time:	Characteristics:
Usually greater than 3 days after administration	Skin rashes (erythema, urticaria, exfoliative dermatitis, Stevens-Johnson syndrome, fixed drug eruption, contact dermatitis, bullous eruptions); serum sickness; hematologic reactions; lupus-like symdrome; vasculitis; drug fever; hepatits, nephropathy

Source: Russo, Mary, and Thompson, Marietta, Chapter 72, Pharmacology of drugs used in venereology. Holmes K, Mardh P, Sparling F, and Wiesner P (eds). *Sexually Transmitted Diseases*. New York, McGraw Hill, pp. 891.

APPENDIX K

CLINIC EMERGENCY CARE EQUIPMENT, SUPPLIES, AND MEDICATIONS

Local practices may dictate the use of alternative emergency care equipment, supplies, and medications. Please consult local emergency care experts and coordinate emergency preparedness with the local emergency medical system.

A copy of the inventory is to be kept on top of the emergency cart or kit. All equipment should be tested periodically.

A. Equipment

1. Crash cart or Emergency kit (with portable IV hanger).
2. AMBU bag (1).
3. Oral airways (medium, large; 1 each).
4. Oral bite blocks (2).
5. Sphygmomanometer (1).
6. Stethoscope (1).
7. Flashlight (1).
8. Oxygen tank or Compressed air tank (with regulator, mask).
9. Endotracheal tube

B. Supplies

1. Tourniquets (4).
2. Syringes (1 cc and 5 cc; 4 each).
3. Intravenous infusion sets with flexible tubing (at least 2).
4. Intravenous catheter placement units (17 gauge and 19 gauge; 2 each).
5. Gauze pads (4" x 4").
6. Adhesive tape (1").
7. Flashlight batteries.

C. Medications (Check Expiration Dates Periodically)

1. Aqueous Epinephrine (1:1000; 1 cc ampules; at least 4; more for medically isolated clinics).
2. Aminophylline (500 mg ampules; 2).
3. Dextrose (5% in water; 500 cc; 2)
4. Diphenhydramine hydrochloride (10 mg/ml; 10 cc vial; 2).
5. Hydrocortisone, sodium succinate (500 mg ampule; 2).
6. Norepinephrine bitartrate (4 mg ampules; 2).
7. Normal saline (1,000 ml bottle; 2).
*8. Smelling salts (1 bottle) or ammonia ampules.

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* Optional

APPENDIX L

STD AND THE MANAGEMENT OF RAPE VICTIMS AND SEXUAL CHILD ABUSE VICTIMS

These recommendations are limited to the management of sexually transmitted infections. Appropriate management of medical-legal aspects, potential pregnancy and physical and psychological trauma are also an integral part of management.

There are no firm data with which to estimate the risk of a sexually-assaulted person contracting a sexually transmitted infection. Based on the prevalence of infections in the general population, the most likely diseases for which these patients are at risk appear to be chlamydial infections, gonorrhea, genital herpes, cytomegalovirus and trichomoniasis. If the offender is at high- risk for having syphilis and hepatitis B, there is an increased risk of the victim acquiring these diseases. In order to minimize any long-term physiological and psychological effects, patients that have been assaulted should obtain a specialized evaluation.

RAPE

Initial examination of the rape victim should include:

- Documentation of a female's contraceptive and menstrual history.
- Cultures for *Neisseria gonorrhoeae* from any potentially infected sites.
- If available, cultures for *Chlamydia trachomatis* from any potentially infected sites.
- Examination of external genitalia for evidence of trauma or preexisting STD.
- Vaginal speculum examination for evidence of mucopurulent cervicitis or abnormal vaginal discharge.
- Microscopic examination of
  a. Gram-stained smear of any mucopurulent cervical discharge for evidence of gonorrhea; and
  b. Wet mount and KOH preparations of vaginal discharge for clue cells, motile trichomonads, and fungal elements.
- A bimanual pelvic examination.
- A serologic test for syphilis.
- A pregnancy test, if appropriate.
- A sample of serum should be frozen and saved for future testing (e.g., for cytomegalovirus or hepatitis B).

The risk of infection after rape, while unknown, is thought to be low. If prophylaxis is to be administered because the physician feels it is indicated or because the patient requests it, the following should be used:

> Tetracycline, 0.5 g by mouth, 4 times a day, for at least 7 days; OR doxycycline, 100 mg by mouth, twice a day, for at least 7 days.
>
> Patients who are either allergic to tetracycline or pregnant should be treated with amoxicillin, 3.0 g, or ampicillin, 3.5 g, each given with 1.0 g of probenecid as a single oral dose.

Patients should be seen for medical followup in 14 days and the aforementioned studies, except for the serologic test for syphilis, repeated. A serologic test for syphilis, six weeks after the incident, is important in cases of assault by individuals who are at high risk for syphilis.

Every effort should be made to establish whether the assailant is infected with an STD. Victims should receive treatment for exposure to an STD which is documented in the assailant.

CHILD ABUSE

Any sexually transmitted infection in a child should be considered as evidence of sexual abuse until proven otherwise. Any child with a sexually transmitted infection, and any child or teenager who reports sexual abuse, should be reported to the appropriate authorities for investigation of possible sexual abuse. Sexually abused children are best managed by a team of professionals experienced in addressing their physical and psychological needs.

The risk of acquisition of a sexually transmitted infection in child victims of sexual assault or abuse is believed to be lower than in adult victims. Such children should be evaluated for STD pathogens as described under the guidelines for management of rape victims but with particular sensitivity to clinical procedures which may be traumatic to them.

Treatment is indicated when disease is present. However, prophylactic treatment prior to diagnosis is usually not indicated unless there is evidence that the assailant is infected.

APPENDIX M

CALCULATION FOR NUMBER OF CLINICIANS NECESSARY FOR CLINIC

Data Needed:

X = estimated time spent with male patient by clinician as fraction of an hour; example: 15 minutes = .25 hrs.
Y = estimated time spent with female patient by clinician as fraction of an hour; example: 20 minutes = .33 hrs.
A = Total Number of Male Patients Examined/Day
B = Total Number of Female Patients Examined/Day
C = Total Clinic Hours/Days

Calculation:

$X \times A$ = Total Male Utilization Time
$Y \times B$ = Total Female Utilization Time
$(X \times A) + (Y \times B)$ = Total Patient Utilization Time
$\frac{(X \times A) + (Y \times B)}{C}$ = Total Clinicians Needed/Day

NOTE: This calculation assumes that patients will present at a constant rate, i.e., no "clumping."

APPENDIX N

JOB DESCRIPTION

Position Title: STD Nurse Clinician

Position Purpose: Functions in an extended role providing primary care to patients who have or are suspected or having one or more sexually transmitted diseases (STD), under the medical supervision of the clinic physician.

Reportability: Reports to the Clinic Manager

PRINCIPLE RESPONSIBILITIES:

- Provide direct care to patients requesting services, including examination, diagnosis, and treatment under an approved protocol.
- Consult with the clinic physician, according to the clinic guidelines, for patients with diagnostic problems or complications or for any other medical circumstances not covered in the written protocol.
- Provide patient education regarding the disease process, treatment, necessary follow-up examinations, and the importance of sex partner examination.
- Refer patients to other appropriate community resources when findings indicate problems beyond the scope of the STD Clinic.
- Refer patients for disease intervention follow-up according to established clinic guidelines.
- Triage for proper counseling and referral symptomatic patients who can not be examined and treated during clinic hours.
- Document all patient records, forms, and reports thoroughly and according to the requirements for each.
- Assist in training other health care professionals and new clinic staff.
- Conduct routine chart reviews on patient medical records as a part of the ongoing Quality Assurance process.
- Participate in staff meetings and continuing education programs sponsored by the clinic or other designated agency.
- Manage emergencies as they occur in the clinic under a standardized protocol authorized by a clinic physician.
- Perform other related duties as assigned.

APPENDIX O

PERFORMANCE STANDARDS FOR STD CLINICIANS

Distinguished Performance: Observed Performance and quality assurance record audits determine that in *all* instances the clinician meets *each* expectation under *every* STD clinical care category cited below.

Commendable Performance: Observed performance and quality assurance record audits determine that with only rare exception the clinician meets each expectation under every STD clinical care category cited below.

Competent Performance: Observed performance and quality assurance record audits determine that on most occasions (over 95% of cases) the clinician meets each expectation under every STD clinical care category cited below and that laspes are not repeated after attention is called to them.

Unacceptable Performance: Observed performance and quality assurance record audits determine that: (1) in less than 95% of cases the clinician meets each expectation under every STD clinical care category cited below; (2) laspes are repeated even after attention is called to them; or (3) both.

Clinical Care Categories

1. **Basic medical history for an initial examination** shall include:
   a. Reason for attendance;
   b. Problem description (present symptom(s), STD or symptoms in sex partner(s), and past history of similar symptoms);
   c. Past history of STD (including type of STD, dates, treatment and outcome);
   d. Review of recent sexual activity (date of last sexual exposure, exposure site(s), number of partners in past month and sexual preference;
   e. Women only: date of LMP, unusual aspects of LMP, and birth control method;
   f. Drug allergies; and,
   g. Recent antibiotic or "other drug" use (type, purpose, duration).

2. **Routine physical examination** shall include:
   a. Inspection of the skin of the face, trunk, forearms, palms, soles, groin and thighs;
   b. Inspection of the oral mucosa and pharynx;
   c. Inspection of the pubic hair for lice and nits;
   d. **Females:**
      — Inspection of external genitalia, perineum and anus;
      — Examination of the vagina and cervix using a speculum;
      — Bimanual pelvic examination (checking for cervical motion tenderness, palpation of uterus and adnexae;
   e. **Males:**
      — Inspection of penis, including meatus, retraction of foreskin and expression of any discharge from urethra;
      — Palpation of scrotal contents;
   f. Inspection of the anus, if indicated as an exposed site; and,
   g. Palpation for inguinal and femoral lymphadenopathy (other nodes to be palpated in the gay and bisexual male include cervical, epitrochlear, supraclavicular and axillary).

3. **Routine laboratory specimens collected for female patients** shall include:
   a. Serologic test for syphilis (if the patient is not epidemiologically related to a syphilis case and has no history of a negative within 1 month);
   b. Culture for gonorrhea from all exposed sites;
   c. Pap smear (if clinic policy to perform) if not done within past year, or if most recent Pap smear is abnormal; and,
   d. Endocervical Gram-stain (if indicated).

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4. **Routine laboratory specimens collected for male patients** shall include:
   a. Serologic test for syphilis (if the patient is not epidemiologically related to a syphilis case and has no history of a negative within 1 month);
   b. Urethral Gram-stain and culture; and,
   c. Cultures for gonorrhea from all exposed sites.

5. **Additional evaluation when indicated by routine history and/or physical findings** shall include:
   a. PID, mucopurulent cervicitis of high risk groups;
   b. Vaginal discharge;
   c. Pregnancy;
   d. Nongonococcal urethritis or contact;
   e. Unexplained cervical or vaginal lesion;
   f. Confirmed or suspected syphilis contact;
   g. Lesions thought to be a chancre;
   h. Rash thought to be secondary syphilis; and,
   i. Other STD.

6. **Treatment shall be in accordance with CDC recommended treatment schedules.**

7. **Referrals shall include all areas listed under Clinic Protocols for Patient Managements in Part I of the CDC Quality Assurance Guidelines for STD Clinics - 1985.**

8. **Followup for Test-of-cure** shall include:
   a. History
      — Symptom response and current problems;
      — Drug reaction(s);
      — Compliance with previous instruction;
      — Sexual exposure since therapy; and,
      — Treatment status of partner.
   b. Followup physical examination; and,
   c. Appropriate laboratory.

9. **Patients record documentation** shall include:
   a. All areas listed above; and,
   b. Signature of clinician.

10. **Patient counseling** shall include:
   a. Results and interpretation of all tests;
   b. Name of disease and how it is transmitted;
   c. Names of the medications and why they are used;
   d. How much medicine and when, specifically, to take it;
   e. Expected outcome of treatment;
   f. Potential side effects and what to do about them;
   g. Description of behaviors and conditions that will assure treatment efficacy and avoid side effects of treatment;
   h. Symptoms of and response to apparent treatment failure; and,
   i. Necessity of abstaining from sex until all treatment completed, TOC, and partners treated.

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